UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No.1456 Master File No. 01-CV-12257-PBS Subcategory No. 06-CV-11337-PBS
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, et al.*, Civil Action No. 07-10248-PBS	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler

PLAINTIFFS' REPLY TO ROXANE'S RESPONSE TO THE UNITED STATES' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED FACTS

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PRELIMINARY STATEMENT

The United States makes the following general reply to Roxane's Response to the United States' Local Rule 56.1 Statement of Undisputed Material Facts as to the Roxane Defendants (MD 6424) (Roxane's 56.1 "Response").

As an initial matter, nothing in Roxane's 56.1 Response creates a genuine dispute of material fact. For example, Roxane takes issue with terms used by the United States (e.g., "multi-source") as vague, ambiguous and/or undefined, although such terms were used by their own witnesses. Such quibbling does not go to the substance of the United States' cited facts. Roxane likewise claims that certain expert declarations relied on by the United States are "unsupported by citations to the record." Roxane, however, cites no authority for the proposition that expert declarations need to include citations to the record, or that expert declarations themselves are not record evidence.

The United States believes that it is readily apparent that responses such as these do not create a genuine dispute of material fact. Accordingly, rather than go through Roxane's 56.1 Response adding yet a third statement at every numbered paragraph, the United States has only included a specific reply where it believes a reply or correction will be of assistance in showing there is no genuine dispute as to the fact asserted in the first instance by the United States.

I. INTRODUCTION

1. The United States hereby incorporates by reference the United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants ("US-C-SF"), filed this date.

Roxane's Response: This paragraph does not state a purported undisputed fact and therefore no response is required. Roxane hereby incorporates by reference Defendants' Response to the United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants.

2. Defendant Roxane Laboratories, Inc., n/k/a Boehringer Ingelheim Roxane, Inc. ("BIRI") is a corporation organized under the laws of the state of Delaware with its principal offices in Columbus, Ohio. In or around April 2005, Roxane Laboratories, Inc. changed its name from Roxane Laboratories, Inc. to BIRI. (United States' First Amended Complaint (hereinafter, "Amended Complaint"), ¶ 15 and Roxane's Answer and Defenses to the First Amended Complaint (hereinafter "Answer"), ¶ 15) BIRI continues to manufacture pharmaceutical products. (Corrected Roxane Local Rule 56.1 Statement of Undisputed Material Facts In Support of Its Motion For Summary Judgment (Dkt. No. 6207) (hereinafter "Roxane SOF"), ¶ 96)

Roxane's Response: Undisputed.

3. Defendant Roxane Laboratories, Inc. is a corporation organized under the laws of Nevada, and was incorporated therein in or around April 2005. (Roxane SOF, ¶ 96) As of that time, Roxane Laboratories, Inc., assumed responsibilities for sales and marketing of pharmaceutical products sold under the Roxane trade name. (*Id.*) For the purposes of this Statement of Facts, BIRI and Roxane Laboratories, Inc. are referred to collectively as "Roxane."

Roxane's Response: Undisputed.

4. Roxane's five-digit labeler code is 00054.

Roxane's Response: Undisputed.

5. In or around 1991, Roxane signed a Medicaid Rebate Agreement with the Secretary of Health and Human Services. (Roxane SOF at ¶¶ 124-25)

Roxane's Response: Undisputed.

A. The Drugs At Issue

6. The Amended Complaint alleges claims against Roxane arising from reimbursement paid by Medicare and Medicaid to providers for dispensing varying dosages, concentrations and sizes of nine Roxane products: azathioprine, diclofenac sodium, furosemide, hydromorphone, ipratropium bromide, Oramorph SR, Roxanol, Roxicodone and sodium polystyrene sulfonate (the "Subject Drugs"). (Amended Complaint, ¶ 58)

Roxane's Response: Undisputed that the Government's Amended Complaint in this case purports to allege claims against Roxane arising from reimbursement paid by Medicare and Medicaid to providers for dispensing certain forms of the nine products listed, and specifically

for the products listed by NDC number in paragraph 8 of this Statement of Facts (the "Subject Drugs"). Disputed that the Government's claims in this case have merit and disputed that the Government is entitled to recovery on any of its claims. Disputed that the Government is pursuing any claim related to Medicare reimbursement for any drug other than ipratroprium bromide.

7. Although all of the Subject Drugs are multiple-source drugs, Roxane markets several of its products as "branded generics," meaning that Roxane assigns the products a "brand name" and markets them as "branded products." (Declaration of James J. Fauci in Support of Plaintiff's Motion for Partial Summary Judgment and in Opposition to the Roxane Defendants' Motion for Partial Summary Judgment (hereinafter, "Fauci") Exhibit 1 (5/21/2008 Mark Shaffer Dep.), at 66:11 - 67:3; Fauci Exhibit 2 (1/27/2005 Sheldon Berkle Dep.), at 129:11 - 129:20) Roxane distinguished internally between its "multi-source" products and its "branded generic" products. (*Id.*; *see also* Roxane SOF, ¶ 113)

Roxane's Response: Roxane disputes that all of the Subject Drugs over the entire relevant timeframe were "multiple-source" drugs in part because the term is vague, ambiguous and undefined in the Government's fact and in part because at certain times, certain strengths and package sizes of certain of the drugs may have only been available from Roxane (*e.g.* Roxicodone 15 mg and 30 mg strengths) or did not have a bio-equivalent competitor (*e.g.* Oramorph). (*See* United States' Local Rule 56.1 Statement of Undisputed Material Fact as to the Roxane Defendants ("US Roxane SOF") at ¶ 98 and Roxane's Response to the United States' Local Rule 56.1 Statement of Undisputed Material Fact as to the Roxane Defendants ("Roxane Resp. to US Roxane SOF") at ¶ 89) Undisputed that the Subject Drugs were "multiple-source" in that they all faced competition from a bio-equivalent or therapeutically equivalent competitor.

Roxane also disputes the Government's statement that "Roxane markets several of its products as 'branded generics'" both because the term is vague, ambiguous and undefined and because the Government has not specified which Subject Drugs it believes were marketed as "branded generics." As Mr. Colin Carr-Hall explained when asked what the term "branded generic" means: "That's a challenging one because I think it means different things to different people." (Tab 222, 12/12/08 Carr-Hall Dep. 73-74) Indeed, Roxane witnesses have testified to several different definitions of the term. (*Compare, e.g.* Tab 222, 12/12/08 Carr-Hall Dep. 74-75 ("my interpretation of a branded generic" includes both "an older brand with generic competitors" and a generic drug that has "a name that it has some name recognition") to Tab 258, 5/21/08 Shaffer Dep. 66 ("My definition of a branded generic is a generic product that is given a brand name and promoted like a brand.")) In addition, certain drugs were classified as "branded generics" by some witnesses and as "brands" by other witnesses. (*See, e.g.*, Tab 269, 10/18/05 Via Dep. 54-55 (considered Oramorph, Roxanol and Roxicodone "branded" drugs); Tab 221, 1/27/05 Berkle Dep. 24-25 (Roxicodone was a branded generic, not a brand); Tab 246, 11/10/04 Paoletti Dep. 260-61 (Roxicodone was on "branded side"); Tab 243, 11/19/04 Mayhew Dep. 102-04 (Oramorph, Roxicodone, Roxicet were "branded generics"))

Undisputed, however, that Roxane distinguished internally for marketing purposes between what it called "multi-source" products and the "branded/branded generic" products that were part of the palliative care product line marketed to physicians by a physicians' sales force. (*See* Tab 246, 11/10/04 Paoletti Dep. 260-61 ("Roxane at one time had products that we considered the multisource products . . .and then there were other products that were represented by a physician field sales force . . .[and] they were responsible for maybe another half a dozen products that were the branded . . ."); Tab 259, 8/5/08 Shaffer Dep. 363 (physician sales force promoted brand/branded generic products, not generic products like azathioprine); Tab 276,5/10/07 Waterer Dep. 254-55; Tab 282, ROXMA045921-23, 1/12/99 Letter from D. Lanzillotta to P. Pelanek) With regard to the Subject Drugs, Oramorph, Roxicodone and Roxanol were considered part of the branded/branded generics line within Roxane. (Tab 269, 10/18/05 Via Dep. 86-87; Tab 258, 5/21/08 Shaffer Dep. 28, 55; Tab 246, 11/10/04 Paoletti Dep. 260-61) The rest of the Subject Drugs – ipratropium bromide, azathioprine, hydromorphone, furosemide, diclofenac sodium and sodium polystyrene sulfonate – were part of what Roxane called its multisource line. For purposes of summary judgment (including for purposes of Roxane's Statement of Facts, its Responses to the Government's Statement of Facts with regard to Roxane and its replies to the Government's Responses to Roxane's Statement of Facts), when the term "multisource"or "multiple-source" is used, Roxane will interpret it to mean and apply to only the six drugs listed here that Roxane considered part of its multi-source line of products unless otherwise noted. Roxane disputes any suggestion or inference from this paragraph that it considered the Novaplus-label ipratropium bromide products to be brands or branded generic products. At all times, Roxane considered Novaplus ipratropium bromide to be a generic product. (*See* Roxane's Corrected Local Rule 56.1 Statement of Undisputed Material Facts in Support of its Motion for Summary Judgment ("Roxane SOF") at ¶¶ 135-47)

8. The following are the NDCs for the Subject Drugs:

Subject Drug	**Formulation**	**Strength/Package Size**	**NDC**
azathioprine	Tablet	50 mg (100x) (10 x 10)	00054-4084-25
diclofenac sodium	Tablet	50 mg (100x) (10 x 10)	00054-4221-25
diclofenac sodium	Tablet	75 mg (100x) (10 x 10)	00054-4222-25
furosemide	Solution	60 ML	00054-3294-46
furosemide	Solution	120 ML	00054-3294-50
furosemide	Tablet	20 mg 100s (10 x 10)	00054-4297-25
furosemide	Tablet	20 mg UD	00054-4297-25
furosemide	Tablet	20 mg 1000s	00054-4297-31
furosemide	Tablet	40 mg 100s (10 x 10)	00054-4299-25

furosemide	Tablet	40 mg 100s UD	00054-8299-25
furosemide	Tablet	40 mg 1000s	00054-4299-31
furosemide	Tablet	80 mg 100s (10 x 10)	00054-4301-25
furosemide	Tablet	80 mg 100s UD	00054-8301-25
furosemide	Tablet	80 mg 500s	00054-4301-29
hydromorphone	Tablet	2 mg 100s (4 x 25)	00054-4392-25
hydromorphone	Tablet	4 mg 100s (4 x 25)	00054-4394-25
ipratropium bromide .02%	Solution	2.5 ml 25s	00054-8402-11
ipratropium bromide .02%	Solution	2.5 ml 30s	00054-8402-13
ipratropium bromide .02%	Solution	2.5 ml 60s	00054-8402-21
ipratropium bromide .02%, NOVAPLUS	Solution	2.5 ml 25s	00054-8404-11
ipratropium bromide .02%, NOVAPLUS	Solution	2.5 ml 30s	00054-8404-13
ipratropium bromide .02%, NOVAPLUS	Solution	2.5 ml 60s	00054-8404-21
Oramorph SR	Tablet	15 mg 100s (4 x 25)	00054-4790-25
Oramorph SR	Tablet	30 mg 50s	00054-4805-19
Oramorph SR	Tablet	30 mg 100s (4 x 25)	00054-4805-25
Oramorph SR	Tablet	30 mg 250s	00054-4805-27
Oramorph SR	Tablet	60 mg 100s	00054-4792-25
Oramorph SR	Tablet	100 mg 100s	00054-4793-25
Roxanol	Solution	20 mg/ml 30 ml	00054-3751-44
Roxanol	Solution	20 mg/ml120 ml	00054-3751-50
Roxanol	Solution	20 mg/ml 240 ml	100 00054-3751-58
Roxicodone	Tablet	15 mg 100s (4 x 25)	00054-4658-25

Roxicodone	Tablet	30 mg 100s (4 x 25)	00054-4665-25
sodium polystyrene sulfonate O/S	Oral Sus	15 g/60 ml 500 ml	00054-3805-63
sodium polystyrene sulfonate O/S	Oral Sus	15 g/60 ml 60 ml 10s UD	00054-8816-11

Roxane's Response: Undisputed, except that Roxane notes that the furosemide tablets the Government lists as "20 mg UD" should be described as "20 mg 100s UD" and that the NDC number for this drug is also listed incorrectly; it should be 0054-8297-25, not 0054-4297-25.

B. Roxane's Customers, and Its Sales and Contracting Practices

9. Roxane sells the Subject Drugs to various classes of customers, including wholesalers, retail generic distributors, chain pharmacies, independent pharmacies, homecare pharmacies, hospitals and long term care facilities. (Fauci Exhibit 3 (Declaration of Simon Platt (hereinafter, "Platt Decl.")), ¶ 6; *see also* Fauci Exhibit 4, (3/2/2005 Christine Marsh Dep.) at 67:7 - 68:25)

Roxane's Response: Undisputed that at various times throughout the time period at issue in this case, Roxane has sold the Subject Drugs to various classes of customers, including wholesalers, distributors, chain pharmacies, independent pharmacies, homecare pharmacies, hospitals and long term care facilities. Disputed that Roxane sold all the Subject Drugs to all classes of customers. For instance, the Novaplus ipratropium bromide products were sold by Novation GPO exclusively to Novation GPO's hospital members. (Roxane SOF at ¶¶ 141-42, 148-49; US Resp. to Roxane SOF at ¶ 149)

Disputed that Roxane sold each Subject Drug throughout the entire time period at issue in this case or currently sells all of the Subject Drugs. For example, Roxane divested Oramorph SR, Roxicodone and Roxanol in September 2001, and discontinued its Novaplus-label ipratropium bromide products in or around March 2004. (Roxane SOF at ¶¶ 150, 253; US Response to Roxane SOF at ¶ 150) Also disputed that Roxane sold the Subject Drugs to a class of customers termed "retail generic distributors."

10. Roxane sells its drugs through two primary distribution channels – direct sales and indirect sales. (Fauci Exhibit 3 (Platt Decl.), ¶¶ 4, 7) In a direct sale, Roxane invoices its customer for a product and then ships the product directly to that customer. (*Id.*) Wholesalers and chain drug stores that warehouse their own product typically purchase products directly from Roxane. (Fauci Exhibit 4 (3/2/2005 Christine Marsh Dep.), at 67:18 - 68:6; Fauci Exhibit 3 (Platt Decl.), ¶ 9)

Roxane's Response: Undisputed. However, Roxane objects to the Plaintiff's alleged

facts because they are not supported by citations to the record as required by Local Rule 56.1. The Government cites to an expert declaration in support of the alleged facts, but the expert declaration is unsupported by citations to the record. (Fauci Ex. 3, Declaration of Platt (filed under seal) at ¶¶ 4, 7 and 9) *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006) (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule 56.1).

UNITED STATES' REPLY: Roxane cites no authority for the proposition that expert declarations need to include citations to the record, or that expert declarations themselves are not record evidence. The single case cited by Roxane, *O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006), holds only that statements of fact offered in support of summary judgment cannot include "conclusory statements" and must be supported by record evidence. Federal Rule 56 plainly provides that motions for summary judgment may be supported by affidavits, so long as those affidavits "set out facts that would be admissible into evidence." Fed. R. Civ. P. 56(c) and (e)(1). As the Platt Declaration sets out facts that would be admissible into evidence, Roxane has no basis to dispute statements of fact on the ground that they rely on Mr. Platt's affidavit and opinions. *See*, *e.g.*, *Iacobelli Const., Inc. v. County of Monroe*, 32 F.3d 19, 25 (2d Cir. 1994) ("An affidavit stating the facts upon which the expert's opinion is based satisfies rule 56(e) even if the data supporting the facts is not attached.")

11. Roxane's direct customers generally purchase products at contractual prices, and are invoiced directly by Roxane. (Fauci Exhibit 3 (Platt Decl.), ¶ 7) Direct customers may also receive product discounts or price reductions in the form of rebates, special sale prices and/or other price adjustments which effectively reduce the net amounts paid for the product being purchased. (*Id*., ¶ 8)

Roxane's Response: Roxane objects to the Plaintiff's alleged facts because they are not supported by citations to the record as required by Local Rule 56.1. The Government cites to an expert declaration in support of the alleged facts, but the expert declaration is unsupported by citations to the record. (Fauci Ex. 3, Declaration of Platt (filed under seal) at ¶¶ 7 and 8) *See O'Brien*, 440 F. Supp. 2d at 5 n.1 (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule

56.1). Undisputed that Roxane's direct customers sometimes purchase products at contractual prices and are invoiced directly by Roxane. Disputed that Roxane's direct customers only purchase products at contractual prices. Roxane's direct customers, such as wholesalers, also purchase products at wholesale acquisition cost. (Roxane SOF at ¶ 109) Undisputed that Roxane's direct customers may also receive product discounts or price reductions in the form of rebates, special sale prices and/or other price adjustments which effectively reduce the net amounts paid for the product being purchased.

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 10.

12. An indirect sale can be a sale that takes place between Roxane's wholesale customer and a contract customer who does not take direct delivery of the product from Roxane. (Fauci Exhibit 4 (3/2/2005 Christine Marsh Dep.), at 68:19 - 68:25; Fauci Exhibit 3 (Platt Decl.), ¶ 4) The indirect customer takes delivery of Roxane's product from the wholesaler. (Fauci Exhibit 3 (Platt Decl.), ¶ 10)

Roxane's Response: Undisputed. However, Roxane objects to the Plaintiff's alleged facts because they are not supported by citations to the records as required by Local Rule 56.1. The Government cites to an expert declaration in support of the alleged facts, but the expert declaration is unsupported by citations to the record. (Fauci Ex. 3, Declaration of Platt (filed under seal) at ¶¶ 4 and 10) *See O'Brien*, 440 F. Supp. 2d at 5 n.1 (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule 56.1).

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 10.

13. In an indirect sale with a contract, Roxane negotiates a contract with an indirect customer which sets forth the price between Roxane and the indirect customer. This contract price is nearly always less than the invoice price Roxane originally charges the wholesaler. (*Id.*; *see also* Fauci Exhibit 5 (1/31/2003 Edward Tupa Dep.), at 148:20 - 149:10) In order to compensate the wholesaler for the shortfall that results from servicing indirect contract customers at prices below the wholesaler's original invoice price, the wholesaler is provided a credit for the difference, also known as a "chargeback." (Fauci Exhibit 3 (Platt Decl.), ¶ 10; *see also* Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 440:18 - 441:2; Fauci Exhibit 7 (12/1/2005 Edward DiPaola Dep.), at 75:22 - 76:10)

Roxane's Response: Undisputed that in some indirect sales with a contract, Roxane negotiates a contract with indirect customers which sets forth the price between Roxane and the

indirect customer. Disputed that in all indirect sales with a contract, Roxane negotiates a contract with indirect customers. In some indirect sales with a contract, Roxane negotiates a contract with a Group Purchasing Organization, source program, or similar program of which the indirect customer is a member, and that contract sets forth the price between Roxane and the indirect customer. (Tab 258, 5/21/08 Shaffer Dep. 67-68; Tab 235, 11/4/05 Gordon Dep. 37-38; Tab 248, 7/26/07 Paoletti Dep. 43) Roxane does not dispute the second and third sentences of the Government's alleged fact. Roxane objects to the Government's citation to the expert declaration of Simon Platt as the declaration is not supported by citations to the record as required by Local Rule 56.1 (Fauci Ex. 3, Declaration of Platt (filed under seal) at ¶ 10) *See O'Brien*, 440 F. Supp. 2d at 5 n.1 (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule 56.1).

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 10.

14. Wholesalers may also receive product discounts or price reductions in the form of rebates, special sales prices and/or other price adjustments which effectively reduce the net amounts paid for the pharmaceuticals. (Fauci Exhibit 3 (Platt Decl.), ¶ 11) Cardinal Health, Inc. ("Cardinal"), one of the three largest national wholesalers, measures its ultimate acquisition price of a product on a "dead net" basis, which is the price actually paid by Cardinal when factoring in rebates, chargebacks and other discounts. (Fauci Exhibit 8 (6/17/2008 Matthew Erick 30(b)(6) Dep.), at 118:11 - 119:22)

Roxane's Response: Roxane disputes and objects to the Government's alleged fact that "[w]holesalers may also receive product discounts or price reductions" on grounds that it is unsupported by citations to the record, as is required by Local Rule 56.1. The Government cites to an expert declaration in support of this alleged fact, but the expert declaration in unsupported by citations to the record. (Fauci Ex. 3, Declaration of Platt (filed under seal) at ¶ 11) *See O'Brien*, 440 F. Supp. 2d at 5 n.1 (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule 56.1). Roxane disputes that the Government's alleged fact that "[w]holesalers may also receive product discounts or price reductions" is material to the Government's motion for summary judgment as the alleged fact is not specific to Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005) (refusing to consider a summary judgment movant's immaterial facts).

Undisputed that the Cardinal Health witness testified that Cardinal Health calculates its acquisition price net of wholesaler chargebacks, rebates, and other discounts, but disputed that

this alleged fact is material to the Government's motion for summary judgment against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

15. Cardinal does not charge indirect customers more than the contract price negotiated between the manufacturer and the indirect customer; instead, Cardinal honors the price as set forth in the indirect contract. (*Id*., at 245:18 - 248:5) McKesson Corporation ("McKesson"), another of the three largest national wholesalers, also honors the indirect contract price negotiated between a manufacturer and its indirect contract customer. (Fauci Exhibit 9 (10/15/2004 Kimbir Tate 30(b)(6) Dep.), at 11:22 - 14:13)

Roxane's Response: Roxane does not dispute that Cardinal and McKesson witnesses testified that Cardinal and McKesson honor the indirect contract prices negotiated between a manufacturer and its indirect contract customers. Roxane disputes that the Government's alleged fact is material to the Government's motion for summary judgment as the alleged fact is not specific to Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

16. Wholesalers profit from servicing indirect contracts through the manufacturer's payment of an administrative fee or rebate. (Fauci Exhibit 8 (6/17/2008 Matthew Erick 30(b)(6) Dep.), at 246:21 - 247:20)

Roxane's Response: Disputed. The Government's proffered evidence does not support the alleged fact. The cited deposition testimony only refers to "purchase rebates" paid by manufacturers to wholesalers for distributing that manufacturer's drugs and makes no mention of administrative fees. Indeed, the Cardinal Health deponent cited by the Government made clear that Cardinal Health does not charge administrative fees to manufacturers. (Tab 231, 6/17/08 Erick Dep. 135-36, 192-94) Also disputed to the extent the Government's alleged fact applies to any wholesaler other than Cardinal Heath as the proffered citation to the record only pertains to Cardinal Health. Roxane also disputes that the Government's alleged fact is material to the Government's motion for summary judgment as the alleged fact is not specific to Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

UNITED STATES' REPLY: The testimony relied on by the United States establishes

that Cardinal Health profits from servicing indirect contracts through the manufacturer's payment of a five percent rebate. Mr. Erick, Cardinal's corporate designee, testified as follows:

> Q. And I believe you testified that in that situation of an indirect contract, Cardinal receives typically generally a five percent rebate. Is that correct?
> A. Distributing –
> (Objection to form)
> Q. Go ahead.
> A. For distributing the product.
> Q. Right. And who pays the five percent rebate?
> A. The manufacturer.

(Fauci Exhibit 8 (6/17/2008 Matthew Erick 30(b)(6) Dep.), at 246:21 - 247:20)

17. Roxane was aware that wholesaler margins were typically less than 5%. (Fauci Exhibit 101 (Roxane "Reimbursement Background" memorandum), at Paoletti 20752 (noting that "a wholesaler's margin for most products is only a marginal 1% - 2% over their acquisition cost"); Fauci Exhibit 11 (12/4/2008 Robert Sykora Dep.), at 208:7 - 210:5)

Roxane's Response: Disputed. The Government's proffered evidence does not support the alleged fact that Roxane was aware that wholesaler margins were typically less than 5%. While Fauci Exhibit 101 notes that "a wholesaler's margin for most products is now only a marginal 1% -2% over their acquisition cost," it does not indicate whether someone at Roxane wrote the Reimbursement Background memorandum, and the testimony from Mark Shaffer indicates that an agency outside of Roxane may have wrote it. (Tab 258, 5/21/08 Shaffer Dep. 241- 43) Moreover, Fauci Exhibit 101 only indicates that in 2000 wholesaler margins were typically 1- 2%, and, in the same memorandum, the author states that wholesaler margins had previously been 20-25%, without indicating the time frame.

In addition, the testimony of Mr. Sykora cited by the Government does not evidence that Roxane was aware during the relevant time period that wholesaler margins were typically less than 5%. Mr. Sykora had previously worked for Cardinal Health, a wholesaler, in a generic drug contracting capacity. (Tab 263, 12/4/08 Sykora Dep. 9-12) It is therefore not surprising that Mr. Sykora is knowledgeable about the wholesaler markups provided by Cardinal Health. The questioning cited by the Government only pertained to Mr. Sykora's experience while employed at Cardinal Health, not about Roxane's corporate understanding of wholesaler markups or about practices at wholesalers other than Cardinal Health. Mr. Sykora was not testifying as a corporate representative of Roxane. Indeed, Roxane's corporate representatives and other employees have testified that Roxane typically does not pay attention to or know the amount of wholesaler margins, as they do not see the invoice or agreement between the wholesaler and the retailer. (Tab 276, 5/9/07 Waterer Dep. 89-93; Tab 258, 5/21/08 Shaffer Dep. 182; Tab 248, 7/26/07

Paoletti Dep. 42-43)

UNITED STATES' REPLY: The fact that the Reimbursement Background memorandum "may" have been written by "an agency outside of Roxane" is irrelevant to whether Roxane was aware that wholesaler margins were typically less than 5%. The Reimbursement Background memorandum was circulated to Roxane's "Palliative Care Sales Team" by Mark Shaffer, who was the head of Roxane's palliative care sales force. Mr. Shaffer testified that he read the memorandum prior to circulating it (Fauci Reply Exhibit 182 (5/21/2007 Shaffer Dep.), at 241:4 - 246:8), and sales personnel were specifically advised to review the material contained in the Reimbursement Background memorandum. (Fauci Exhibit 101, at Bates Number Paoletti-20748)

II. ROXANE REPORTED AWPs TO THE PRICING COMPENDIA FOR THE SUBJECT DRUGS

18. From at least 1996 to the present, Roxane reported Average Wholesale Prices ("AWPs") for the Subject Drugs to various pricing compendia, including Red Book, First Data Bank and Medi-Span. (Roxane SOF, ¶ 112; *see also* Fauci Exhibit 12 (11/17/2004 Richard Feldman Dep.), at 190:1 - 190:19; Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 518:11 - 518:14; Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 94:10 - 95:5, 245:1 - 245:12; Fauci Exhibit 5 (1/31/2003 Edward Tupa Dep.), at 67:7 - 67:9, 224:16 - 224:19)

Roxane's Response: Undisputed that Roxane provided AWPs for the Subject Drugs that it sold, and had not divested or discontinued, to various pricing compendia, including Red Book, First DataBank and Medi-Span, from at least 1996 to the present.

19. Employees in Roxane's marketing department periodically reviewed price listings from First Data Bank to verify AWPs for Roxane's products. (Fauci Exhibit 24 (11/9/2004 Leslie Paoletti Dep.), at 108:21 - 109:18; Fauci Exhibit 19 (11/30/2005 Leslie Paoletti Dep.), at 126:1 - 126:17; Fauci Exhibit 20 (10/24/2001 Judith Waterer Dep.), at 234:25 - 235:20)

Roxane's Response: Undisputed that employees in Roxane's marketing department periodically reviewed listings from First DataBank and verified AWPs for Roxane's products,

but disputed to the extent the Government's fact implies that Roxane employees reviewed every listing received from First Databank or verified AWPs for all Roxane drugs on each listing.

20. Roxane employees similarly reviewed price listings from Red Book to verify Roxane's AWPs. (*See*, *e.g.*, Fauci Exhibit 21)

Roxane's Response: Undisputed that employees in Roxane's marketing department periodically reviewed listings from Red Book and verified AWPs for Roxane's products, but disputed to the extent the Government's fact implies that Roxane employees reviewed every listing received from Red Book or verified AWPs for all Roxane drugs on each listing.

21. Roxane typically reported AWPs to the pricing compendia at the time of a product's launch and whenever AWPs changed. (Roxane SOF, ¶ 112; *see also* Fauci Exhibit 22 (9/20/2005 Leslie Paoletti Dep.), at 81:15 - 85:10; Fauci Exhibit 23)

Roxane's Response: Undisputed.

III. ROXANE'S REPORTED WACS TO THE PRICING COMPENDIA FOR SOME OF THE SUBJECT DRUGS AND FOR SOME TIME PERIODS

22. From at least 1996 to approximately December 1997, Roxane reported Wholesale Acquisition Costs ("WACs") for its "multi-source products" (including azathioprine, diclofenac sodium, furosemide, hydromorphone, ipratropium bromide and sodium polystyrene sulfonate) to various pricing compendia, including First Data Bank and Red Book. (Roxane SOF, ¶ 113; *see infra* ¶¶ 119-125)

Roxane's Response: Undisputed that Roxane provided Wholesale Acquisition Costs for the products listed from at least 1996 until late 1997 or early 1998 to various pricing compendia, including First Data Bank and Red Book.

23. After December 1997, Roxane stopped reporting new WACs for its multi-source products to First Data Bank. (Roxane SOF, ¶ 113) As a result, Roxane's last reported WACs for these products continued to be published by First Data Bank until late 1999. (*See infra* ¶ 124)

Roxane's Response: Undisputed that Roxane stopped providing WACs for its multi-source products at issue to First Data Bank around late 1997/early 1998. Disputed that "[a]s a result, Roxane's last reported WACs for these products continued to be published by First Data Bank until late 1999." This alleged fact is not supported by the Government's proffered evidence. Paragraph 124 *infra* does not support this fact. Moreover, the Government has not cited to any evidence that Roxane caused First DataBank to continue to publish Roxane's last

reported WACs until late 1999, or that Roxane was able to control what First Data Bank published. Rather, Roxane repeatedly asked First Data Bank to stop publishing WACs for its multi-source products. (Tab 275, 11/28/05 Waterer Dep. 239-42) ("[W]e had one heck of a time getting First Data Bank to report correct information. We went through their information and repeatedly told them that they were not reporting the correct information . . . we had been consulting with our legal department to find out whether or not we would have to pursue legal remedy to get them to stop reporting false information. . . . What I took out of this was, here's another example that we have to go back to First Data Bank yet again. We have repeatedly given them the information, but now it's getting to the point where it's becoming a customer or whatever issue, and we have to get them to quit reporting incorrect information. It was very frustrating. We were giving them the right information over and over again. They refused to fix the information.")

24. In or around late 1999, Roxane instructed First Data Bank to stop publishing WACs entirely for its multi-source products. From that point onwards, WACs of $0.00 were published for these products instead. (*See infra* ¶¶ 132-136)

Roxane's Response: Undisputed that Roxane requested that First Data Bank stop publishing WACs for its multi-source WACs, but disputed that the first and only time that Roxane made such a request was in or around late 1999. Rather, Roxane repeatedly asked First Data Bank to stop publishing WACs for its multi-source products. (Tab 275, 11/28/05 Waterer Dep. 239-42 ("[W]e had one heck of a time getting First Data Bank to report correct information. We went through their information and repeatedly told them that they were not reporting the correct information … we had been consulting with our legal department to find out whether or not we would have to pursue legal remedy to get them to stop reporting false information. . . . What I took out of this was, here's another example that we have to go back to First Data Bank yet again. We have repeatedly given them the information, but now it's getting to the point where it's becoming a customer or whatever issue, and we have to get them to quit reporting incorrect information. It was very frustrating. We were giving them the right information over and over again. They refused to fix the information."); Fauci Exhibit 129 (12/7/99 Paoletti Email to Rowenhorst responding to email chain where Waterer writes in a 11/22/99 email "Didn't first Data Bank fix this yet?"); *see also* Resp. to US Roxane SOF at ¶¶ 132-36)) Undisputed that First Data Bank informed Roxane in late 1999 that it would publish a value of $0.00 for all of Roxane's multisource products. However, the Government's proffered evidence does not establish that First Data Bank did actually publish a value of $0.00 (and not, for example, a blank spot) for all of Roxane's multi-source products after 1999 and therefore this fact is disputed.

25. Roxane continued to report WACs for its "branded generic" products (including Roxicodone, Oramorph SR and Roxanol) throughout the relevant time frame. (Roxane SOF, ¶ 113; *see also* Fauci Exhibit 24 (11/9/2004 Leslie Paoletti Dep.), at 94:8 - 94:23; Fauci Exhibit 19 (11/30/2005 Leslie Paoletti Dep.), at 128:8 - 128:17)

Roxane's Response: Undisputed that Roxane continued to provide WACs for Roxicodone, Oramorph SR and Roxanol during the relevant time frame until those products were divested in September 2001. (Roxane SOF at ¶¶ 253-54)

IV. ROXANE'S REPORTED AWPS WERE FALSE

26. The United States' expert, Simon D. Platt, CPA, has calculated Roxane's average sales prices ("ASPs") for the Subject Drugs, aggregating the sales transaction data on a quarterly basis, and net of chargebacks, rebates and discounts. Mr. Platt has calculated ASPs for Roxane's direct sales, and for Roxane's indirect sales. (Fauci Exhibit 3 (Platt Decl.), ¶¶ 12-16) The ASPs, to Roxane's indirect customers represent prices paid by customers who purchase Roxane's products from wholesalers. (*Id*., ¶ 4)

Roxane's Response: Roxane disputes that Mr. Platt's calculation of average sales prices ("ASPs"), which he purportedly based on Roxane's direct and indirect sales, represent Roxane's actual average sales prices for the Subject Drugs. Mr. Platt testified that his calculated ASPs based on Roxane's indirect transaction data did not include transactions involving sales of the Subject Drugs between wholesalers and off-contract customers who did not negotiate contract pricing with Roxane or through a wholesaler source program. (Tab 249, 3/24/09 Platt Dep. 122-25) Mr. Platt further testified that his calculated ASPs are "the average selling prices Roxane has realized in its sales of its products to its customers, not its customers' sales to their customers." (*Id.* at 125) Roxane also disputes that Mr. Platt's calculated ASPs to Roxane's indirect customers represent prices paid by customers who purchased Roxane's products from wholesalers. Mr. Platt testified that he did not analyze whether any actual sales transactions of the Subject Drugs occurred at the ASPs he calculated. (*Id.* at 175)

Roxane further disputes that any facts alleged in paragraph 26 establish that Roxane's reported AWPs were "false," which is legal argument, not fact. *See Mercier v. Boilermakers Apprenticeship and Training Fund*, No. 07-cv-11307, 2009 WL 458556, at *9 (D. Mass. Feb. 10, 2009) (refusing to consider a summary judgment movant's argument reframed as facts). Roxane also incorporates Roxane SOF ¶¶ 99-106.

UNITED STATES' REPLY: Roxane's purported dispute is smoke and mirrors. First, Roxane states (and the United States does not dispute) that Mr. Platt did not calculate average prices of sales between wholesalers and off-contract customers who did not negotiate contract pricing with Roxane. Roxane never had access to transaction data involving those types of sales during its normal course of business and therefore could not have used it for purposes of

reporting prices to the pricing compendia. Roxane nevertheless argues that the United States' experts should have calculated ASPs using wholesaler transaction data obtained through litigation subpoenas to several wholesalers (which Roxane asserts show slightly higher average prices). (*See* Roxane's Tab 249, 3/24/2009 Platt Dep., at 118-124 (questioning whether Mr. Platt might have analyzed transaction data of Cardinal Health).)[1] But this dispute about something that Mr. Platt did *not* do is not a basis for disputing this paragraph, which explains what Mr. Platt *did* do. Mr. Platt used Roxane's own transaction data to calculate average sales prices for Roxane's direct sales, and for Roxane's "indirect sales" (which are sales through wholesalers to retail customers who have negotiated contract pricing with Roxane). (*Id*., at 125) ("My average selling prices are the average selling prices Roxane has realized in its sales of its products to its customers, not its customers' sales to their customers, yes.") In its response, Roxane does not dispute the validity of its own transaction data for its direct or indirect sales, nor does Roxane dispute the accuracy of Mr. Platt's calculations that use Roxane's direct and indirect sales transaction data. Instead, Roxane simply injects confusion in an attempt to avoid any comparison between the prices which Roxane knew its drugs were sold to wholesale and retail customers, and the prices Roxane reported to the compendia. Notably, Roxane does not present any comparison of average sales prices from the wholesaler transaction data to the prices it reported to the compendia, no doubt because doing so would show that Roxane's reported prices were

[1] The Medicare Modernization Act of 2003 requires manufacturers to calculate and report the "*manufacturer's* average sales price," 42 U.S.C. § 1395w-3a(c), and CMS's implementing regulations provide that manufacturers are required to calculate average sales price based on the *manufacturer's* prices, not wholesalers' prices to wholesaler customers. 42 C.F.R. § 414.804 (requiring manufacturers to calculate the "manufacturer's average sales price for a quarter" based on "the manufacturer's sales to all purchasers in the United States for that particular 11-digit National Drug Code.").

substantially in excess of the average sales prices.

Second, Roxane's assertion that Mr. Platt "did not analyze whether any actual sales transactions of the Subject Drugs occurred at the ASPs he calculated" is similarly nothing but an attempt at obfuscation. As Mr. Platt's declaration and testimony make clear, Mr. Platt calculated *average* sales prices on a quarterly basis, not individual sales transaction prices. By definition, an *average* sales price for a given quarter typically will not represent an actual individual transaction price. Roxane's "dispute" is neither genuine nor material.

27. Mr. Platt has also compared Roxane's ASPs to the AWPs and WACs published by First DataBank and Red Book, and has calculated the "spreads" on Roxane's drugs, i.e., the percentage markup over Roxane's ASPs, aggregating the data annually. These calculations and comparisons show that Roxane's AWPs were substantially higher than the prices generally and currently paid in the market for Roxane's products. (*Id*., ¶¶ 12-16 and accompanying graphs and summaries)

Roxane's Response: As previously noted in Roxane's response to Paragraph 26, which is expressly incorporated herein, Roxane disputes that Mr. Platt's calculated ASPs represent Roxane's actual average sales prices for the Subject Drugs based on Roxane's direct and indirect sales. Roxane further disputes that the ASPs as calculated by Mr. Platt represent the "the prices generally and currently paid in the market for Roxane's products." Mr. Platt testified that he did not analyze whether any actual sales transactions of the Subject Drugs occurred at the ASPs he calculated. (Tab 249, 3/24/09 Platt Dep. 175) Because Mr. Platt's calculated ASPs are not actual average selling prices for the Roxane Subject Drugs, Mr. Platt's calculated spreads are invalid and his comparisons do not show that Roxane's AWPs were "substantially higher than prices generally and currently paid in the market for Roxane's products." (*See Id.*) Roxane further disputes that any facts alleged in paragraph 27 establish that Roxane's reported AWPs were "false," and incorporates its Response to ¶ 26.

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 26.

28. The AWPs that Roxane caused to be published for its ipratropium bromide products (NDCs 00054-8402-11, 00054-8402-21 and 00054-8402-13) were substantially higher than the prices at which Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A1 and Summary A1) Specifically, the spreads between Roxane's AWPs and its ASPs for its indirect

sales for these products ranged from 77.6% in 1996 (the year of launch), to 296.8% in 2000, to 494% in 2002. (*Id.*)

Roxane's Response: Roxane disputes the validity of Mr. Platt's calculated ASPs for Roxane's ipratropium bromide products and also disputes the validity of Mr. Platt's calculation of "spreads" based upon his calculated ASPs. Roxane disputes the alleged fact that Mr. Platt's ASPs for its ipratropium bromide products represent the prices at which Roxane sold these products to its indirect customers. Mr. Platt testified that his calculated ASPs based on Roxane's indirect transaction data did not include transactions involving sales of the Subject Drugs between wholesalers and off-contract customers who did not negotiate contract pricing with Roxane or through a wholesaler source program. (Tab 249, 3/24/09 Platt Dep. 122-25) Mr. Platt further testified that his calculated ASPs are "the average selling prices Roxane has realized in its sales of its products to it customers, not its customers' sales to their customers." (*Id.* at 125) Mr. Platt also testified that he did not analyze whether any actual sales transactions of the Subject Drugs occurred at the ASPs he calculated. (*Id.* at 175) Because Mr. Platt's calculated ASPs for ipratropium bromide are not actual average selling prices for the product, Mr. Platt's calculated spreads are invalid and his comparisons do not show that Roxane's AWPs were substantially higher than prices generally and currently paid in the market for Roxane's products. Roxane further disputes that any facts alleged in paragraph 28 establish that Roxane's reported AWPs were "false," and incorporates its Response to ¶ 26.

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 26.

29. The AWPs that Roxane caused to be published for its azathioprine (NDC 00054-4084-25) product were substantially higher than the prices at which Roxane sold this product to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A2 and Summary A2) Specifically, the spreads between Roxane's AWPs and its ASPs for its indirect sales for this product ranged from 95.6% in 1999 to 356.9% in 2002. (*Id.*)

Roxane's Response: Roxane disputes the validity of Mr. Platt's calculated ASPs for Roxane's azathioprine products and also disputes the validity of Mr. Platt's calculation of "spreads" based upon his calculated ASPs. Roxane disputes the alleged fact that Mr. Platt's ASPs for its azathioprine products represent the prices at which Roxane sold these products to its indirect customers. Mr. Platt testified that his calculated ASPs based on Roxane's indirect transaction data did not include transactions involving sales of the Subject Drugs between wholesalers and off-contract customers who did not negotiate contract pricing with Roxane or through a wholesaler source program. (Tab 249, 3/24/09 Platt Dep. 122-25) Mr. Platt further testified that his calculated ASPs are "the average selling prices Roxane has realized in its sales of its products to it customers, not its customers' sales to their customers." (*Id.* at 125) Mr. Platt also testified that he did not analyze whether any actual sales transactions of the Subject Drugs

occurred at the ASPs he calculated. (*Id.* at 175) Because Mr. Platt's calculated ASPs for azathioprine are not actual average selling prices for the product, Mr. Platt's calculated spreads are invalid and his comparisons do not show that Roxane's AWPs were substantially higher than prices generally and currently paid in the market for Roxane's products. Roxane further disputes that any facts alleged in paragraph 29 establish that Roxane's reported AWPs were "false," and incorporates its Response to ¶ 26.

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 26.

30. The AWPs that Roxane caused to be published for its sodium polystyrene sulfonate products (NDCs 00054-3805-63 and 00054-8861-11) were substantially higher than the prices at which Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A3 and Summary A3) Specifically, the spreads between Roxane's AWPs and its ASPs for its indirect sales for these products ranged from 194.5% in 2000 to 196.1 % in 2002. (*Id.*)

Roxane's Response: Roxane disputes the validity of Mr. Platt's calculated ASPs for Roxane's sodium polystyrene sulfonate products and also disputes the validity of Mr. Platt's calculation of "spreads" based upon his calculated ASPs. Roxane disputes the alleged fact that Mr. Platt's ASPs for its sodium polystyrene sulfonate products represent the prices at which Roxane sold these products to its indirect customers. Mr. Platt testified that his calculated ASPs based on Roxane's indirect transaction data did not include transactions involving sales of the Subject Drugs between wholesalers and off-contract customers who did not negotiate contract pricing with Roxane or through a wholesaler source program. (Tab 249, 3/24/09 Platt Dep. 122-25) Mr. Platt further testified that his calculated ASPs are "the average selling prices Roxane has realized in its sales of its products to it customers, not its customers' sales to their customers." (*Id.* at 125) Mr. Platt also testified that he did not analyze whether any actual sales transactions of the Subject Drugs occurred at the ASPs he calculated. (*Id.* at 175) Because Mr. Platt's calculated ASPs for sodium polystyrene sulfonate are not actual average selling prices for the product, Mr. Platt's calculated spreads are invalid and his comparisons do not show that Roxane's AWPs were substantially higher than prices generally and currently paid in the market for Roxane's products. Roxane further disputes that any facts alleged in paragraph 30 establish that Roxane's reported AWPs were "false," and incorporates its Response to ¶ 26.

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 26.

31. The AWPs that Roxane caused to be published for its Oramorph SR products (NDCs 00054-4793-25, 00054-4792-25, 00054-4805-25, 00054-4790-25, 00054-4805-27 and 00054-4805-19) were substantially higher than the prices at which

Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A4 and Summary A4) Specifically, the spread between Roxane's AWPs and its ASPs for its indirect sales for these products ranged from 69.4% in 1999 to 72.3% in 2000. (*Id*.)

Roxane's Response: Roxane disputes the validity of Mr. Platt's calculated ASPs for Roxane's Oramorph SR products and also disputes the validity of Mr. Platt's calculation of "spreads" based upon his calculated ASPs. Roxane disputes the alleged fact that Mr. Platt's ASPs for its Oramorph SR products represent the prices at which Roxane sold these products to its indirect customers. Mr. Platt testified that his calculated ASPs based on Roxane's indirect transaction data did not include transactions involving sales of the Subject Drugs between wholesalers and off-contract customers who did not negotiate contract pricing with Roxane or through a wholesaler source program. (Tab 249, 3/24/09 Platt Dep. 122-25) Mr. Platt further testified that his calculated ASPs are "the average selling prices Roxane has realized in its sales of its products to it customers, not its customers' sales to their customers." (*Id.* at 125) Mr. Platt also testified that he did not analyze whether any actual sales transactions of the Subject Drugs occurred at the ASPs he calculated. (*Id.* at 175) Because Mr. Platt's calculated ASPs for Oramorph SR are not actual average selling prices for the product, Mr. Platt's calculated spreads are invalid and his comparisons do not show that Roxane's AWPs were substantially higher than prices generally and currently paid in the market for Roxane's products. Roxane further disputes that any facts alleged in paragraph 31 establish that Roxane's reported AWPs were "false," and incorporates its Response to ¶ 26.

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 26.

32. The AWPs that Roxane caused to be published for its furosemide products (NDCs 00054-4299-31, 00054-4297-31, 00054-4301-29, 00054-3294-46, 00054-4301-25, 00054-3294-50, 00054-8299-25, 00054-4297-25, 00054-4299-25, 00054-8297-25 and 00054-8301-25) were substantially higher than the prices at which Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A5 and Summary A5) Specifically, the spreads between Roxane's AWPs and its ASPs for its indirect sales for these products ranged from 156.8% in 1999 to 1411.9% in 2001. (*Id*.)

Roxane's Response: Roxane disputes the validity of Mr. Platt's calculated ASPs for Roxane's furosemide products and also disputes the validity of Mr. Platt's calculation of "spreads" based upon his calculated ASPs. Roxane disputes the alleged fact that Mr. Platt's ASPs for its furosemide products represent the prices at which Roxane sold these products to its indirect customers. Mr. Platt testified that his calculated ASPs based on Roxane's indirect transaction data did not include transactions involving sales of the Subject Drugs between wholesalers and off-contract customers who did not negotiate contract pricing with Roxane or

through a wholesaler source program. (Tab 249, 3/24/09 Platt Dep. 122-25) Mr. Platt further testified that his calculated ASPs are "the average selling prices Roxane has realized in its sales of its products to it customers, not its customers' sales to their customers." (*Id.* at 125) Mr. Platt also testified that he did not analyze whether any actual sales transactions of the Subject Drugs occurred at the ASPs he calculated. (*Id.* at 175) Because Mr. Platt's calculated ASPs for furosemide are not actual average selling prices for the product, Mr. Platt's calculated spreads are invalid and his comparisons do not show that Roxane's AWPs were substantially higher than prices generally and currently paid in the market for Roxane's products. Roxane further disputes that any facts alleged in paragraph 32 establish that Roxane's reported AWPs were "false," and incorporates its Response to ¶ 26.

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 26.

33. The AWPs that Roxane caused to be published for its hydromorphone products (NDCs 00054-4394-25 and 00054-4392-25) were substantially higher than the prices at which Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A6 and Summary A6) Specifically, the spreads between Roxane's AWPs and its ASPs for its indirect sales for these products ranged from 241.1 % in 1999 to 314.3% in 2001. (*Id.*)

Roxane's Response: Roxane disputes the validity of Mr. Platt's calculated ASPs for Roxane's hydromorphone products and also disputes the validity of Mr. Platt's calculation of "spreads" based upon his calculated ASPs. Roxane disputes the alleged fact that Mr. Platt's ASPs for its hydromorphone products represent the prices at which Roxane sold these products to its indirect customers. Mr. Platt testified that his calculated ASPs based on Roxane's indirect transaction data did not include transactions involving sales of the Subject Drugs between wholesalers and off-contract customers who did not negotiate contract pricing with Roxane or through a wholesaler source program. (Tab 249, 3/24/09 Platt Dep. 122-25) Mr. Platt further testified that his calculated ASPs are "the average selling prices Roxane has realized in its sales of its products to it customers, not its customers' sales to their customers." (*Id.* at 125) Mr. Platt also testified that he did not analyze whether any actual sales transactions of the Subject Drugs occurred at the ASPs he calculated. (*Id.* at 175) Because Mr. Platt's calculated ASPs for hydromorphone are not actual average selling prices for the product, Mr. Platt's calculated spreads are invalid and his comparisons do not show that Roxane's AWPs were substantially higher than prices generally and currently paid in the market for Roxane's products. Roxane further disputes that any facts alleged in paragraph 33 establish that Roxane's reported AWPs were "false," and incorporates its Response to ¶ 26.

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 26.

34. The AWPs that Roxane caused to be published for its NovaPlus ipratropium bromide products (NDCs 00054-8404-11, 00054-8404-13 and 00054-8404-21) were substantially higher than the prices at which Roxane sold these products to the hospital class of trade. (Fauci Exhibit 3 (Platt Decl.), Graph A 7 and Summary A 7) Specifically, the spreads between Roxane's AWPs and its ASPs for its indirect sales for these products ranged from 306.3% in 2000 to 440.7% in 2002. (*Id*.)

Roxane's Response: Roxane disputes the validity of Mr. Platt's calculated ASPs for Roxane's Novaplus ipratropium bromide products and also disputes the validity of Mr. Platt's calculation of "spreads" based upon his calculated ASPs.

Roxane further disputes the materiality of Mr. Platt's calculated ASPs for Roxane's Novaplus ipratropium bromide products because it is undisputed that it is highly unlikely that Novaplus ipratropium bromide was ever reimbursed under Medicare Part B. (Rox. SOF ¶¶ 151-55; US Resp. to Roxane SOF at ¶¶ 151-55) Further, "only 48 NovaPlus prescriptions were paid for by the Medicaid program throughout the U.S." from 1998 through 2004. (*Id*) Also, Mr. Platt testified that his calculated ASPs based on Roxane's indirect transaction data did not include transactions involving sales of the Subject Drugs between wholesalers and off-contract customers who did not negotiate contract pricing with Roxane or through a wholesaler source program. (Tab 249, 3/24/09 Platt Dep. 122-25) Mr. Platt further testified that his calculated ASPs are "the average selling prices Roxane has realized in its sales of its products to it customers, not its customers' sales to their customers." (*Id.* at 125) Mr. Platt also testified that he did not analyze whether any actual sales transactions of the Subject Drugs occurred at the ASPs he calculated. (*Id.* at 175) Because Mr. Platt's calculated ASPs for NovaPlus ipratropium bromide are not actual average selling prices for the product, Mr. Platt's calculated spreads are invalid and his comparisons do not show that Roxane's AWP's were substantially higher than prices generally and currently paid in the market for Roxane's products. Roxane further disputes that any facts alleged in paragraph 34 establish that Roxane's reported AWPs were "false," and incorporates its Response to ¶ 26.

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 26.

35. The AWPs that Roxane caused to be published for its Roxanol products (NDCs 00054-3751-50, 00054-3751-44 and 00054-3751-58) were substantially higher than the prices at which Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A8 and Summary A8) Specifically, the spreads between Roxane's AWPs and its ASPs for its indirect sales for these products ranged from 211.6% in 1999 to 239.2% in 2000. (*Id*.)

Roxane's Response: Roxane disputes the validity of Mr. Platt's calculated ASPs for

Roxane's Roxanol products and also disputes the validity of Mr. Platt's calculation of "spreads" based upon his calculated ASPs. Roxane disputes the alleged fact that Mr. Platt's ASPs for its Roxanol products represent the prices at which Roxane sold these products to its indirect customers. Mr. Platt testified that his calculated ASPs based on Roxane's indirect transaction data did not include transactions involving sales of the Subject Drugs between wholesalers and off-contract customers who did not negotiate contract pricing with Roxane or through a wholesaler source program. (Tab 249, 3/24/09 Platt Dep. 122-25) Mr. Platt further testified that his calculated ASPs are "the average selling prices Roxane has realized in its sales of its products to itcustomers, not its customers' sales to their customers." (*Id.* at 125) Mr. Platt also testified thathe did not analyze whether any actual sales transactions of the Subject Drugs occurred at the ASPs he calculated. (*Id.* at 175) Because Mr. Platt's calculated ASPs for Roxanol are not actual average selling prices for the product, Mr. Platt's calculated spreads are invalid and his comparisons do not show that Roxane's AWPs were substantially higher than prices generally and currently paid in the market for Roxane's products. Roxane further disputes that any facts alleged in paragraph 35 establish that Roxane's reported AWPs were "false," and incorporates its Response to ¶ 26.

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 26.

36. The AWPs that Roxane caused to be published for its diclofenac sodium products (NDCs 00054-4222-25 and 00054-4221-25) were substantially higher than the prices at which Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A9 and Summary A9) Specifically, the spreads between Roxane's AWPs and its ASPs for its indirect sales for these products ranged from 795.5% in 2000 to 1069.6% in 2001. (*Id*.)

Roxane's Response: Roxane disputes the validity of Mr. Platt's calculated ASPs for Roxane's diclofenac sodium products and also disputes the validity of Mr. Platt's calculation of "spreads" based upon his calculated ASPs. Roxane disputes the alleged fact that Mr. Platt's ASPs for its diclofenac sodium products represent the prices at which Roxane sold these products to its indirect customers. Mr. Platt testified that his calculated ASPs based on Roxane's indirect transaction data did not include transactions involving sales of the Subject Drugs between wholesalers and off-contract customers who did not negotiate contract pricing with Roxane or through a wholesaler source program. (Tab 249, 3/24/09 Platt Dep. 122-25) Mr. Platt further testified that his calculated ASPs are "the average selling prices Roxane has realized in its sales of its products to it customers, not its customers' sales to their customers." (*Id.* at 125) Mr. Platt also testified that he did not analyze whether any actual sales transactions of the Subject Drugs occurred at the ASPs he calculated. (*Id.* at 175) Because Mr. Platt's calculated ASPs for diclofenac sodium are not actual average selling prices for the product, Mr. Platt's calculated spreads are invalid and his comparisons do not show that Roxane's AWPs were substantially higher than prices generally and currently paid in the market for Roxane's products. Roxane

further disputes that any facts alleged in paragraph 36 establish that Roxane's reported AWPs were "false," and incorporates its Response to ¶ 26.

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 26.

37. The AWPs that Roxane caused to be published for its Roxicodone products (NDCs 00054-4665-25 and 00054-4658-25) were substantially higher than the prices at which Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A10 and Summary A10) Specifically, the spread between Roxane's AWPs and its ASPs for its indirect sales for these products was 102% in 2000. (*Id.*)

Roxane's Response: Roxane disputes the validity of Mr. Platt's calculated ASPs for Roxane's Roxicodone products and also disputes the validity of Mr. Platt's calculation of "spreads" based upon his calculated ASPs. Roxane disputes the alleged fact that Mr. Platt's ASPs for its Roxicodone products represent the prices at which Roxane sold these products to its indirect customers. Mr. Platt testified that his calculated ASPs based on Roxane's indirect transaction data did not include transactions involving sales of the Subject Drugs between wholesalers and off-contract customers who did not negotiate contract pricing with Roxane or through a wholesaler source program. (Tab 249, 3/24/09 Platt Dep. 122-25) Mr. Platt further testified that his calculated ASPs are "the average selling prices Roxane has realized in its sales of its products to it customers, not its customers' sales to their customers." (*Id.* at 125) Mr. Platt also testified that he did not analyze whether any actual sales transactions of the Subject Drugs occurred at the ASPs he calculated. (*Id.* at 175) Because Mr. Platt's calculated ASPs for Roxicodone are not actual average selling prices for the product, Mr. Platt's calculated spreads are invalid and his comparisons do not show that Roxane's AWPs were substantially higher than prices generally and currently paid in the market for Roxane's products. Roxane further disputes that any facts alleged in paragraph 37 establish that Roxane's reported AWPs were "false," and incorporates its Response to ¶ 26.

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 26.

V. ROXANE KNOWINGLY REPORTED FALSE AWPS FOR THE PURPOSE OF INCREASING REIMBURSEMENT TO PROVIDERS WHO PURCHASED ROXANE'S PRODUCTS

38. Roxane's stated practice was to set the AWP for its multi-source drugs at 10% below the AWP of the corresponding branded/innovator drug at the time of launch. (Roxane SOF, ¶ 99; *see also* Fauci Exhibit 20 (10/24/2001 Judith Waterer

Dep.), at 242:22 - 243:14; Fauci Exhibit 24 (11/9/2004 Leslie Paoletti Dep.), at 79:18 - 79:24, 147:20 - 147:25) For many products, however, including several of the Subject Drugs (e.g., hydromorphone), the AWP was *not* set at 10% below the corresponding brand's AWP at the time of launch. (*See, e.g.*, Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 587:16 - 58:6)

Roxane's Response: Undisputed that Roxane's general practice was to set the AWP for its multi-source drugs at 10% below the corresponding brand's AWP at the time of launch. Disputed that Roxane's stated practice was to always, with no exceptions, set AWP at 10% below the corresponding brand's AWP at the time of launch. For example, if Roxane is late to the market and there are many other generic competitors, Roxane may set its AWP at launch at or around the same level of the generic competitors instead of at the brand AWP minus 10%. (Roxane SOF at ¶ 105) Disputed that "[f]or many products, however, including several of the Subject Drugs (*e.g.* hydromorphone), the AWP was *not* set at 10% below the corresponding brand's AWP at the time of launch." The Government's proffered evidence does not support this alleged fact, as it references only one Roxane drug, hydromorphone. Moreover, hydromorphone was launched before the relevant time period, and therefore the way in which its AWP was set at launch is immaterial to the Government's motion for summary judgment. (*See* Fauci Exhibit 56, July 1998 Monthly Report at RLI-AWP-00316337, wherein an AWP increase for hydromorphone was being discussed in July 1998, which demonstrates that the product was launched before July 1998.) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

39. When Roxane set the AWP at 10% below the AWP of the corresponding branded/innovator product, it did so in order to increase reimbursement for its products. For example, an October 11, 1996 inter-office memorandum sent by Ms. Waterer to Mr. Tupa proposed increasing the AWP on metaproterenol (which is not a Subject Drug) as part of a "relaunch" of the product:

> Because this is a "re-launch" we already have a published AWP on the record. We have an opportunity to raise our AWP to 10% off the brand for the re-launch. This would provide us with a competitive advantage, particularly as the product does not appear to be subject to HCFA MAC pricing yet. In addition to being the innovator's generic, we could also be the most profitable product to the pharmacist.

(Fauci Exhibit 26) According to Ms. Waterer's memorandum, Roxane's three generic competitors had AWPs which were set lower than 10% off the branded AWP. Specifically, the branded AWP was $43.23, and Roxane's generic

competitors' AWPs were $30.75, $29.95, and $34.40, respectively. (*Id.*) Ms. Waterer proposed that Roxane raise its AWP from $30.85 to $34.83 to gain the "competitive advantage," but she noted that Roxane could raise the AWP even higher (to $39.91), which would be 10% off the brand AWP. (*Id.*)

Roxane's Response: Disputed that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane because it does not relate to one of the Subject Drugs at issue in this case and it did not occur during the timeframe relevant to the Government's claims. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

Disputed that Roxane's reason for generally setting the AWP for its drugs at 10% below the brand's AWP was to increase reimbursement for its products. This alleged fact is not supported by the Government's proffered evidence. The government's cited document, Fauci Exhibit 26, merely indicates that in deciding where to place the AWP for metaproterenol (not a Subject Drug) in the unique situation of a re-launch, Roxane took into consideration the fact that a higher AWP would place Roxane in a better competitive position. Nothing in this cited document indicates that the reason for Roxane's general practice of setting its AWP at 10% below the brand's AWP is in order to increase reimbursement. Rather, the evidence shows that Roxane generally set its AWPs at 10% below the brand because this was industry practice and Roxane was following industry practice. (Roxane SOF at ¶¶ 99-100) Further, nothing in this cited document indicates that as a general matter setting AWP at 10% below the AWP of the brand's AWP would in fact increase reimbursement for most drugs, including the Subject Drugs. In addition, the evidence in the record demonstrates that generally when Roxane set an AWP for a drug that already had other generic competitors, Roxane set the AWP at or around the same level of its generic competitors. (Roxane SOF at ¶ 105)

UNITED STATES' REPLY: Roxane fails to explain what is "unique" about a "re-launch" or why the fact that Fauci Exhibit 26 refers to a "relaunch" is important. The evidence plainly shows that Ms. Waterer regarded raising Roxane's "AWP to 10% off the brand" as providing Roxane with a "competitive advantage." (Fauci Exhibit 26)

40. When launching a product into an "existing market," Roxane's stated practice is to set the AWP at a level comparable to competitors' AWPs. (Roxane SOF, ¶ 105; *see also* Fauci Exhibit 22 (9/20/2005 Leslie Paoletti Dep.), at 26:10 - 27:14) Mr. Russillo testified that Roxane considered AWP spreads in setting and reporting prices. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 66:19 - 67:16)

Roxane's Response: Undisputed that when launching a product into an existing market, Roxane would generally set the AWP at a level comparable to the generic competitors' AWPs. Disputed that Roxane's stated practice was to always, with no exceptions, set the AWP at a level comparable to competitors' AWPs when launching a product into an "existing market." Disputed that Mr. Russillo testified that Roxane considered AWP spreads in reporting prices. This alleged fact is not supported by the Government's proffered evidence, Fauci Exhibit 13. Undisputed that Mr. Russillo testified that Roxane considered AWP spreads in setting prices. However, when asked if Roxane set AWPs at a large level to increase the profitability of its products to customers, Mr. Russillo said that he would not agree with that phrasing, and that rather, Roxane merely recognized that spread was important because a pharmacist would only substitute a generic drug for a brand drug if it was more profitable to do so. (Tab 253, 1/8/09 Russillo Dep. 67-69). In addition, Mr. Russillo was not testifying as a corporate representative. Roxane's corporate representative testified that Roxane competed on contract price, and it was not Roxane's general practice to concern itself with the spread except in the "exceptional case" where it was brought to their attention that Roxane's AWPs were out of line with the norm. (Tab 276, 5/9/07 Waterer Dep. 103-04)

> Q. Has Roxane ever concerned itself with the spread as it relates to the pharmacists' reimbursement?
>
> A. If there was an exceptional instance where our pricing was out of line – I think I talked about, I believe it was Furosemide – in an exceptional case where it was brought to our attention, we might take steps to bring ourselves into the average or norm of what everybody else is doing. But in the industry, most everybody's pricing is set very similar so that the spread issue isn't something that generally comes up. If everybody's pricing is in the same average area, you're competing on the contract price. That's generally what occurs in the negotiation.
>
> Q. So it's your testimony that Roxane has never concerned itself with the competitor's price and tried to market the spread to gain market share away from that competitor?
>
> A. It – again, on a very rare instance, there may have been something that had to do with the difference in AWPs. It would not be our general practice. It would be a very rare occasion.

(*Id.*)

41. Roxane states that it generally did not change the AWPs for its multi-source drugs following launch, but that it has raised its AWP to match those of competitors, either because Roxane's AWP was not set at 10% below the AWP of the branded/innovator product at the time of launch, or because competitors' AWPs

had increased. (Roxane SOF, ¶ 106; *see also* Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 586:7 - 589:1; Fauci Exhibit 27 (5/9/2007 Judith Waterer 30(b)(6) Dep.), at 387:16 - 387:24; Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 252:9 - 253:22) Roxane raised the AWPs for several of the Subject Drugs, including hydromorphone (*see infra* ¶¶ 60-63), azathioprine (*see infra* ¶¶ 64-73) and furosemide (*see infra* ¶¶ 74-88).

Roxane's Response: Undisputed that Roxane did not generally change the AWPs for its multi-source drugs following launch. Undisputed that Roxane has, in certain instances, raised its AWP when its AWP was out of line with the rest of its generic competitors, and bringing it in line would allow Roxane to compete fairly. (Fauci Ex. 6, 4/1/03 Waterer Dep. 586-89) Roxane also at times raised an AWP if its drug became a sole-source drug. (Roxane SOF at ¶ 106) Undisputed that Roxane raised the AWPs for hydromorphone, azathioprine and furosemide. Roxane incorporates by reference its Responses to ¶¶ 60-63 (explaining the hydromorphone situation; ¶¶ 64-73 (explaining the azathioprine situation) and ¶¶ 74-88 (explaining the furosemide situation), *infra*.

A. The Launch of Ipratropium Bromide

42. Ipratropium bromide is the generic version of Atrovent Unit Dose Vial ("Atrovent"), a branded drug marketed by Roxane's sister company (BIPI). (Fauci Exhibit 28 (10/31/2008 Sheldon Berkle Dep.), at 77:1 - 77:5)

Roxane's Response: Undisputed that Roxane's ipratropium bromide inhalation solution at issue in this case was the generic version of the branded product, Atrovent, which was marketed by Boehringer Ingelheim Pharmaceuticals, Inc.

43. BIPI lost patent exclusivity on Atrovent in September 1996. (Fauci Exhibit 29, at ROX-TX 01341)

Roxane's Response: Undisputed.

44. Roxane launched its generic ipratropium bromide product preemptively in June 1996, several months prior to other generic manufacturers being able to enter the ipratropium bromide market. (Fauci Exhibit 28 (10/31/2008 Sheldon Berkle Dep.), at 81:17 - 82:08, and at Berkle Dep. Exhibits 7 and 8) In launching generic ipratropium bromide, Roxane's objective was "to capitalize on the narrow window of exclusivity for [ipratropium bromide] in the targeted markets, maintaining a majority of the market share for [the Boehringer Ingelheim Corporation]." (Fauci Exhibit 29 (4/17/1996 Ipratropium Bromide Launch Plan), at Rox TX 01343; Fauci Exhibit 28 (10/31/2008 Sheldon Berkle Dep.), at 111:6 - 111:16)

Roxane's Response: Undisputed that Roxane launched its first generic ipratroprium bromide inhalation solution (.02% solution, 2.5ml Unit Dose Vials in packages of 25, NDC 00054-8402-11 ("IBUDV 2.5ml 25s")) in June 1996, three months before BIPI lost patent exclusivity on Atrovent and other generic manufacturers could enter the market. Undisputed that the marketing plan for this ipratropium bromide product contains the statement quoted by the Government except that there are no brackets around "the Boehringer Ingelheim Corporation" in the document. The Government's quotation, however, is selective and incomplete; the document in its entirety is the best evidence of its content.

45. In or around January 1996, Roxane retained Mark Pope as a consultant to help with the launch of generic ipratropium bromide. (Fauci Exhibit 30 (4/14/2003 Mark Pope Dep.), at 67:25 - 68:17; Fauci Exhibit 5 (1/31/2003 Edward Tupa Dep.), at 40:24 - 41:3, 45:1 - 45:22) Mr. Pope previously had worked for Dey Laboratories, and had experience marketing to the home health care market. (Fauci Exhibit 30 (4/14/2003 Mark Pope Dep.), at 42:3 - 42:9; Fauci Exhibit 5 (1/31/2003 Edward Tupa Dep.), at 40:24 - 41:3)

Roxane's Response: Undisputed that Roxane retained Mark Pope, as a consultant in or around January 1996 to help with Roxane's launch of IB UDV 2.5ml 25s because he was knowledgeable about the home health care market, an important target market for ipratropium bromide with which Roxane did not have much experience. (Fauci Ex. 5, 1/31/03 Tupa Dep. 40-41) Undisputed that Mr. Pope was a former Dey Laboratories employee, but disputed that this fact is material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In fact, Mr. Tupa testified that Mr. Pope's experience at Dey "had nothing to do" with Roxane hiring him as a consultant. (Tab 266, 1/31/03 Tupa Dep. 43-44)

46. On or about January 24, 1996, Mr. Pope met with representatives of Roxane and BIPI regarding the approaching launch of generic ipratropium bromide. (Fauci Exhibit 33, at RLI-AWP-00299558) The topic of "Medicare reimbursement" was discussed at the meeting including, specifically, whether Medicare reimbursed for the product using one or several "J codes." (*Id*., at RLI-AWP-00299559 and RLI-AWP-00299562) BIPI previously had researched "Medicare Regions & Atrovent Solution Reimbursement" in late 1995 but in light of "contradictory information" on this topic, it was agreed that Mr. Pope would "verify reimbursement issues with his contacts within the industry." (*Id*.; Fauci Ex. 110)

Roxane's Response: Undisputed that a meeting occurred on January 24th among Roxane, BIPI and Mark Pope regarding the "approaching generic launch of Ipratropium Bromide UDV." (Fauci Ex. 33, Tupa Fax to Berkle re IB UDV Generic Launch Home Health Care

Market Meeting Summary at RLIAWP-00299558) The document does not state the year in which the meeting took place and the document itself is not dated, but other dates referenced throughout the document are 1996 dates and Roxane does not dispute that it is likely that the date refers to January 24, 1996.

Undisputed that Fauci Exhibit 33 indicates that the issue of "Medicare reimbursement" arose during the January 24th meeting and that the document contains the language quoted by the Government. The Government's quotations, however, are selective, incomplete and misleading; the document in its entirety is the best evidence of its content. The entire referenced paragraph when read in conjunction with Fauci Exhibit 110, which documents BIPI's prior research of the identified Medicare issue, establishes that the discussion and BIPI's prior research related solely to which J-code providers use for reimbursement of ipratropium bromide vs. compounded ipratropium, and this was the only Medicare reimbursement issue Mr. Pope was planning to verify with his contacts:

> There were several issues that arose during the conversation that should be noted and addressed once more research has been completed. The first issue is Medicare reimbursement. Joe was under the impression that the four regions all reimbursed in different ways. He provided his inter-office memo to illustrate the differences from region to region. The key point was that he believes some of the regions are reimbursing brand Atrovent and compounded Ipratropium under different J codes. This is in contrast to the information gathered by Roxane, while researching another matter. Ed Tupa asked Alex Dusek to verify the information we had received in the past was correct. Alex verified that there is only one J code for reimbursement for Atrovent/Ipratropium, J7645 "Ipratropium bromide 0.2%, per ml,inhalation solution, administered through a DME." In light of the contradictory information that was presented it was decided that Mark Pope would verify reimbursement issues with his contacts within the industry."

(Fauci Ex. 33, Tupa Fax to Berkle re IB UDV Generic Launch in Home Health Care Market Meeting Summary at RLI-AWP-00299559) At the meeting, there was no discussion of the formula used by Medicare to calculate reimbursement or the role of AWP in Medicare reimbursement. As such, the facts cited by the Government are not material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co*., 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

47. Following the January 24, 1996 meeting, Mr. Pope researched the home health care market, and met confidentially with "key homecare market customers" to confirm issues regarding packaging and pricing. (Fauci Exhibit 34) Mr. Pope reported his findings to Mr. Edward Tupa (then Roxane's Director of Multi-

Source Marketing) including that "Medicare reimbursement runs approximately 60%." (*Id*., at RLI-AWP-00087618; Fauci Exhibit 35; *see also* Fauci Exhibit 32 (4/2/2003 Thomas Via Dep.), at 144:20 - 144:25)

Roxane's Response: Roxane does not dispute that Mr. Pope met with or contacted various homecare market participants in early 1996 and reported on those discussions to Mr. Tupa. (*See, for example*, Fauci Ex. 34, 1/26/96 Pope Letter to Tupa; Fauci Ex. 35, 2/13/96 Pope Letter to Tupa; Fauci Ex. 36, 3/4/96 Pope Letter to Tupa; Fauci Ex. 37, 2/23/96 Pope Letter to Tupa) Roxane disputes the Government's characterizations of the referenced documents and notes that the Government's quoted phrases are selective and incomplete; the documents in their entirety are the best evidence of their content. Fauci Exhibit 34 does not state that Mr. Pope had "researched the home health care market" or that he had "met confidentially with 'key homecare market customers' to confirm issues regarding packaging and pricing." Rather it states that its purpose was to offer his thoughts and suggestions from the prior meeting and "to suggest a short term action plan for the attainment of critical data related to the success of the launch." As part of his plan he was *going to be* "[s]etting up confidential meetings with key homecare market customers and thought leaders to confirm information such as packaging issues, compounding issues, pricing issues and general fact finding." (Fauci Ex. 34, 1/26/96 Pope Letter to Tupa at RLIAWP- 00087617) In addition, while Fauci Exhibit 34 does note that "Medicare reimbursement runs approximately 60%," it was only one of 17 "Home Healthcare Market Points of Interest" Mr. Pope mentioned, and simply means that "the patient load is 60% Medicare." (Fauci Ex. 34, 1/26/96 Pope Letter to Tupa at RLI-AWP-00087618; Fauci Ex. 36, 3/4/96 Pope Letter to Tupa at RLI-AWP-00087600; Fauci Ex. 32, 4/2/03 Via Dep. 144) Mr. Pope's comments do not relate to the formula used by Medicare to calculate reimbursement or the role of AWP in Medicare reimbursement.

48. Mr. Pope also reported that at least some home health care pharmacies were concerned about "reimbursement issues," (Fauci Exhibit 36), and that one pharmacy suggested that "AWP should be set at no lower than 20% less than the brand." (Fauci Exhibit 37) In his correspondence to Mr. Tupa, Mr. Pope stated that he thought setting the AWP at 10% less than the brand would be best. (*Id*.)

Roxane's Response: Disputed that the evidence proffered by the Government supports the alleged fact that "at least some home health care pharmacies were concerned about 'reimbursement issues.'" Fauci Ex. 36, 3/4/96 Pope Letter to Tupa, notes that *only one* home health care participant is "[c]oncerned about reimbursement issues." And this "concern" was just one out of eleven points this customer raised. There is no further elaboration or explanation regarding what the reimbursement concerns were and no indication that they have anything to do with the formula used by Medicare to calculate reimbursement or with Roxane's AWP or prices. Without foundation, this fact is not admissible and not material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire &*

Marine Ins. Co., 379 F. Supp. 2d at 186 n.1. Undisputed that in describing his meeting with one market participant, Mr. Pope stated: "Talley suggests that AWP should be set at no lower than 20% less than the brand. I think 10% would be best." (Fauci Ex. 37, 2/23/96 Pope Letter to Tupa at RLIAWP-00087598) Roxane set the AWP for its IB UDV 2.5ml 25s at launch at 10% below the brand, consistent with its practice and practice in the industry. (Fauci Ex. 29, 4/17/96 T. Via's Ipratropium Marketing Plan at ROX-TX 01344; Roxane SOF at ¶ 99)

UNITED STATES' REPLY: Although admitting that its consultant, Mr. Pope, reported that a potential customer was concerned about "reimbursement issues," Roxane claims this fact is not admissible because it lacks foundation. Specifically, Roxane argues there "is no further elaboration or explanation regarding what the reimbursement concerns were[.]"

Mr. Tupa (then Roxane's Vice President of Marketing and the recipient of the letter in question), testified that he believed Mr. Pope's statement that the customer was concerned about "reimbursement issues" to mean that the customer "has expressed a concern about Medicare or Medicaid reimbursement." (Fauci Reply Exhibit 183 (1/31/2003 Tupa Dep.), at 96:4 - 96:10)

49. Subsequently, Thomas Via (then a Roxane National Account Manager) drafted the launch plan for generic ipratropium bromide, with input from Mr. Pope and Mr. Tupa. (Fauci Exhibit 38 (l0/18/2005 Thomas Via Dep.), at 156:11 - 157:20)

Roxane's Response: Undisputed that Mr. Via drafted the marketing plan for generic ipratropium bromide .02% solution, 2.5 ml Unit Dose Vials in packages of 25, NDC 00054-8402-11 ("IB UDV 2.5 ml 25s"). Disputed that the marketing plan related to the other five ipratropium bromide NDCs at issue in this case.

50. In written comments to the draft launch plan dated April 9, 1996, Mr. Pope advised that it was "likely Roxane could capture a significant portion of the compounding market, providing the price provides a large enough 'spread' to maintain acceptable profit levels." (Fauci Exhibit 40, at ROX-CA 002096) Mr. Pope testified that he was "sure" his work as a consultant for Roxane included "encouraging Roxane to set and report AWPs and WACs that would allow it to create an attractive spread." (Fauci Exhibit 30 (4/14/2003 Mark Pope Dep.), at119:11 - 119:15, 117:10 - 117:22)

Roxane's Response: Undisputed that Mr. Pope's comments on the draft marketing plan for Roxane's IB UDV 2.5ml 25s contained the quoted language, except that the document uses

the word "price" instead of "pricing." Undisputed that Mr. Pope testified as described. Disputed that the marketing plan related to the other five ipratropium bromide NDCs at issue in this case. The Government's quotations, however, are selective, incomplete and misleading; the entirety of the document and Mr. Pope's testimony are the best evidence of their content. As clarified in a later section of the marketing plan, the "spread" being discussed in the plan is the difference between WAC and AWP, not the difference between AWP or reimbursement and actual acquisition cost, which is the "spread" relevant to the Government's claims against Roxane. (Fauci Ex. 29, 4/17/96 T. Via's Ipratropium Marketing Plan at ROX-TX 01344) In addition, at this time, both the AWP and the WAC for Roxane's IB UDV 2.5 ml 25s were published and publicly available; therefore, Roxane could not have had the required intent to deceive the Government required for liability under the FCA. (Roxane SOF ¶¶ at 112-13) As such, this alleged fact is not material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co*., 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes the materiality of this alleged fact to the Government's Medicare claims against Roxane. Because Medicare reimbursed providers for generic drugs based on the median generic AWP, individual manufacturers' AWPs were irrelevant as providers received the same Medicare reimbursement regardless of which manufacturers' product they purchased. Therefore, there was no incentive for manufacturers to "market the spread" based on higher AWP prices. (Tab 254, 5/12/09 Scott Morton Dep. 184-86; Tab 255, 5/13/09 Scott Morton Dep. 321-22, 326; Tab 279, 5/21/09 Williams Dep. 280-81)

Moreover, Roxane's purpose in creating an AWP/WAC spread for ipratropium bromide was to "encourag[e] accounts to convert from the brand name to the generic product as quickly as possible" (Fauci Ex. 29, 4/17/96 T. Via's Ipratropium Marketing Plan at ROX-TX 01344), a goal that CMS itself just recently stated justified AWP to acquisition costs spreads as high as 73%:

> The Report also found that the percentage differences between Part D payments and drug acquisition costs were more than nine times higher for generic drugs than for brand-name drugs. Clinically appropriate generic prescribing is one of the key ways in which the Part D program is able to provide high quality coverage at a reasonable cost to both beneficiaries and the government. We fully encourage the use of generic drugs since their use provides good value to both the beneficiary and the taxpayer, and *we note that incentives are aligned to encourage promotion of generics by community pharmacies*.

(Tab 126, January 2008 OIG Report, "Review of the Relationship Between Medicare Part D Payments to Local, Community Pharmacies and the Pharmacies' Drug Acquisition Costs, A-06-07-00107 at 6 and pg. 1 of App. G (Jan. 2008 OIG Report) (emphasis added))

UNITED STATES' REPLY: Relying exclusively on the opinions of its experts,

Roxane argues that the fact that Mr. Pope encouraged Roxane to "set and report AWPs and WACs that would allow it to create an attractive spread" is not material to the United States' Medicare claims because Medicare reimburses providers for generic drugs based on the median generic AWP. This argument, however, runs contrary to the conduct of Roxane's own employees, who plainly believed that having a favorable spread would help Roxane win Medicare sales. For example, a Sales Strategy document noted that "Roxane's azathioprine, by virtue of its favorable pricing, has a distinct Medicare advantage." (Fauci Exhibit 111; *see also infra* Paragraph 113).

In addition, Roxane offers no evidence to support a finding that CMS ever approved of drug manufacturers reporting inflated AWPs for any drugs reimbursed by Medicare or Medicaid. The report referenced by Roxane at Tab 126 relates *only* to the Medicare Part D Program, which does *not* involve reimbursement of claims by the government. Instead, under Medicare Part D, CMS contracts with "Part D sponsors" to offer prescription drug benefits to eligible individuals, and pharmacies contract with such sponsors to obtain Part D reimbursement for prescription drugs:

> Unlike Parts A and B of the Medicare program, under which Medicare acts as the payer and insurer and generally pays on a fee-for-service basis, the prescription drug benefit [under Medicare Part D] is based on a private market model. The Centers for Medicare & Medicaid Services (CMS) contracts with prescription drug plans and Medicare Advantage plans, which then acts as the payers and insurers for prescription drug benefits. CMS refers to these private entities as Part D sponsors. Retail pharmacies contract with Part D sponsors to obtain reimbursement for prescription drugs dispensed to Part D beneficiaries.

Tab 126, at 1. Accordingly, as neither CMS nor any other government entity sets reimbursement for Medicare Part D drugs, comments made by CMS in reference to an OIG study on the Part D

program are not evidence of CMS' policy regarding reimbursement of pharmaceuticals by Medicare or Medicaid.

51. The generic ipratropium bromide launch plan was finalized on April 17, 1996. (Fauci Exhibit 29) The launch plan described the pricing for generic Ipratropium Bromide as follows:

> Pricing of [ipratropium bromide] will need to follow the traditional parameters of a generic product. Specifically, AWP will be brand less 10%, or $44.06 for the 25 count package; WAC will be AWP less 40%, or $26.44 for the 25 count package. The reason this type of price structure is used for a generic launch is to create an attractive spread between WAC and AWP, encouraging accounts to convert from the brand name to the generic product as quickly as possible. This rapid conversion is necessary in order to protect our position in the market after generic competitors enter the market. It is felt that competitive pressures will drive large home care pharmacies to purchase significant volumes of [ipratropium bromide], once the pricing is driven down to the $0.75 to $0.80 (.75=$18.75/25, .80=20.00/25) per vial level . . .
>
> . . . In a multi-source product launch, one of the most important keys to success is conversion from the brand to your first to market generic, as early as possible during your period of exclusivity. Again, this is done through enticing the accounts with an increased spread between WAC and AWP.

(*Id*., at ROX-TX 01344)

Roxane's Response: Undisputed that the marketing plan for Roxane's IB UDV 2.5 ml 25s is dated April 17, 1996 and that it contains the quoted language. Disputed that the marketing plan related to any other ipratropium bromide NDC at issue in this case. The Government's quotations, however, are selective, incomplete and misleading; the entirety of the document is the best evidence of its content. As is clear from the quoted language, the "spread" being discussed in the plan is the difference between WAC and AWP, not the difference between AWP or reimbursement and actual acquisition cost, which is the only spread relevant to the Government's claims against Roxane. (Fauci Ex. 29, 4/17/96 T. Via's Ipratropium Marketing Plan at ROX-TX

01344) In addition, at this time, both the AWP and the WAC for Roxane's IB UDV 2.5 ml 25 were published and publicly available; therefore, Roxane could not have had the required intent to deceive the Government required for liability under the FCA. (Roxane SOF at ¶¶ 112-13) As such, this alleged fact is not material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co*., 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

In addition, Roxane disputes the materiality of this alleged fact to the Government's Medicare claims against Roxane. Because Medicare reimbursed providers for generic drugs based on the median generic AWP, individual manufacturers' AWPs were irrelevant as providers received the same Medicare reimbursement regardless of which manufacturers' product they purchased. Therefore, there was no incentive for manufacturers to "market the spread" based on higher AWP prices. (Tab 254, 5/12/09 Scott Morton Dep. 184-86; Tab 255, 5/13/09 Scott Morton Dep. 321-22, 326; Tab 279, 5/21/09 Williams Dep. 280-81)

Moreover, as the quote states, Roxane's purpose in creating an AWP/WAC spread for ipratropium bromide was to "encourag[e] accounts to convert from the brand name to the generic product as quickly as possible" (Fauci Ex. 29, T. Via's 4/17/96 Ipratropium Marketing Plan at ROX-TX 01344), a goal that CMS itself just recently stated justified AWP to acquisition costs spreads as high as 73%:

> The Report also found that the percentage differences between Part D payments and drug acquisition costs were more than nine times higher for generic drugs than for brand-name drugs. Clinically appropriate generic prescribing is one of the key ways in which the Part D program is able to provide high quality coverage at a reasonable cost to both beneficiaries and the government. We fully encourage the use of generic drugs since their use provides good value to both the beneficiary and the taxpayer, and *we notethat incentives are aligned to encourage promotion of generics by community pharmacies.*

(Tab 126, January 2008 OIG Report at 6 and pg. 1 of App. G) (emphasis added)

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 51. Further answering, Roxane claims that the launch plan referenced at Fauci Exhibit 29 does not relate to any ipratropium bromide NDC at issue in this case besides "Roxane's IB UDV 2.5 ml 25s" (NDC 00054-8402-11). Roxane is being evasive. The launch plan itself references Roxane's 30-count package (NDC-00054-8402-13), in addition to the 25-count

package. (Fauci Exhibit 29, at ROX-TX-01343) Moreover, the three "8402" ipratropium bromide NDCs at issue in this litigation are three different package sizes of the *same* product. (Fauci Reply Exhibit 184 (10/18/2005 Via Dep.), at 183:23 - 185:18) The AWP for all three package sizes was identical on a per-vial basis. Specifically, the AWP was $44.06 for the 25-count package, $52.87 for the 30-count package, and $105.74 for the 60-count package; the AWP for each package size reflects an AWP of $1.76 per vial. (Fauci Exhibit 49 (listing AWPs for each package size.))

52. Roxane launched its generic ipratropium bromide product on or about June 3, 1996. (Fauci Exhibit 41) At the time of launch, Roxane planned to sell generic ipratropium bromide to warehousing chain pharmacies and home care pharmacies for approximately $23.80, compared to a reported AWP of $44.06. (Fauci Exhibit 29, at ROX-TX 01352; Fauci Exhibit 42)

Roxane's Response: Undisputed that Roxane launched its generic IB UDV 2.5 ml 25s product on or about June 3, 1996. Disputed that this was the launch date for the other ipratropium bromide NDCs at issue in this case. Roxane disputes that "[a]t the time of launch, Roxane planned to sell generic ipratropium bromide to warehousing chain pharmacies and home care pharmacies for approximately $23.80" as the Government's proffered evidence does not support this alleged fact. The documents cited by the Government indicate that in April 1996, at the time the marketing plan was developed and almost two months prior to the actual launch of the product, that Roxane contemplated $23.80 as the price for IB UDV 2.5 ml 25s to warehousing chains and homecare facilities. (Fauci Ex. 29, 4/17/96 T. Via's Ipratropium Marketing Plan at ROX-TX 01352; Fauci Ex. 42, 4/28/96 Via Memo to Tupa at ROX-CA 001981) The Government does not provide any citation for what price was actually offered to warehousing chains or healthcare facilities at the time of launch in June 1996. Undisputed that the AWP for Roxane's IB UDV 2.5 ml 25s was $44.06 at the time of launch, which was 10% off the brand AWP and consistent with Roxane's standard practice and practice in the industry. (Fauci Ex. 42, 4/28/96 Via Memo to Tupa at ROX-CA 001981; Fauci Ex. 29, 4/17/96 T. Via's Ipratropium Marketing Plan at ROX-TX 01344; Roxane SOF at ¶ 99)

UNITED STATES' REPLY: Roxane claims that the United States' proffered evidence does not support the fact that Roxane planned to sell generic ipratropium bromide to warehousing chain pharmacies and home care pharmacies for approximately $23.80. The

ipratropium bromide pricing strategy dated April 28, 1996, plainly states that “”[h]omecare pharmacy will be offered a contract price of $23.80.” (Fauci Exhibit 42). Product offerings (including product offerings accepted by pharmacies) list the “base contract price” as $23.80. (Fauci Exhibit 44).

53. A product announcement dated April 22, 1996 touted Roxane’s ipratropium bromide as the first generic form of Atrovent and encouraged customers to “[c]ompare acquisition cost and AWP.” (Fauci Exhibit 43) Other documents announcing the availability of generic ipratropium bromide identified the AWP and WAC, and invited customers to enter into sole source pricing agreements with Roxane. (*See, e.g.*, Fauci Ex. 44; Fauci Ex. 45)

Roxane’s Response: Undisputed that Fauci Exhibit 43, an April 22, 1996 product announcement, stated Roxane’s IB UDV 2.5 ml 25s was the first generic form of Atrovent and contained the quoted language. The Government’s quotation, however, is selective, incomplete and misleading; the entirety of the document is the best evidence of its content. Specifically, the quote is in the context of how Roxane’s product relates to the brand, Atrovent, and the entire sentence is “Cost Savings – Compare acquisition cost and AWP.” (Fauci Ex. 43, 4/22/96 New Product Announcement re Ipratropium) Taking the entire quotation in context, it conveys that there is a cost savings to the customer as between the brand, Atrovent, and Roxane’s generic ipratropium bromide. Moreover, the Government does not cite to any evidence that this product announcement was ever actually sent to or seen by any potential customers.

Undisputed that other product announcements identified either the AWP or both the AWP and the WAC for Roxane’s IB UDV 2.5 ml 25s, that Fauci Exhibit 44 stated “we are interested in serving your needs for this product through negotiation of a sole source, three year, market protection pricing agreement,” and that Fauci Exhibit 45 stated “[a]dd to source for 10% monthly rebate.” Roxane generally included the AWP and/or contract prices in its product announcements because many customers requested this information. (Tab 283, Response to Interrogatory No. 11, 3/12/08 Boehringer Ingelheim Roxane’s, Inc.’s Answers and Objections to Plaintiff’s Second Set of Interrogatories (*Illinois v. Abbott Labs., et. al*))

54. On or about January 20, 1997, Roxane decreased the WAC for ipratropium bromide from $26.44 to $25.50 and, at the same time, announced an “Enhanced Ipratropium Bromide Loyalty Bonus Program” which doubled the rebates offered to certain customers. (Fauci Exhibit 46) Roxane did not lower the AWP for generic ipratropium bromide at this time. (Fauci Exhibit 3 (Platt Decl.), Summary A1). The decrease in the WAC from $26.44 to $25.50 was published in First Data Bank. (*Id*.)

Roxane's Response: Undisputed that on or around January 20, 1997 Roxane decreased the WAC for its IB UDV 2.5 ml 25s from $26.44 to $25.50 and at the same time announced an enhanced loyalty bonus program that increased loyalty rebates for certain wholesalers from 3% to 6%. (Fauci Ex. 46, 1/20/97 Walsh Letter to Wholesale Customer) Undisputed that Roxane did not lower its AWP on the product at that time consistent with its standard practice and practice in the industry. (Roxane SOF at ¶ 106) Undisputed that the decrease in WAC was published in First Data Bank, again consistent with Roxane's practice at the time. (Roxane SOF at ¶ 113) Roxane, however, objects to Plaintiff's alleged fact because it is not supported by citations to the record as required by Local Rule 56.1. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006) (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule 56.1). The Government cites to an expert declaration in support of these alleged facts, but the expert declaration is unsupported by citations to the record. (Fauci Ex. 3, Declaration of Platt (filed under seal) at Summary A1) The expert declaration also incorrectly lists the previous WAC in effect as $26.50 rather than $26.44. (*Id.*) Further answering, at the time of the referenced ipratropium bromide WAC change, DeyLaboratories had just launched its competitor generic ipratropium bromide with a WAC price of $25.50. Roxane's new WAC price was set to meet Dey's WAC price. (Tab 284, January 1997 Dey Letter to Wholesaler at RLI-AWP 00361324)

UNITED STATES' REPLY: Roxane cites no authority for the proposition that expert declarations need to include citations to the record, or that expert declarations themselves are not record evidence. The single case cited by Roxane, *O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006), holds only that statements of fact offered in support of summary judgment cannot include "conclusory statements" and must be supported by record evidence. Federal Rule 56 plainly provides that motions for summary judgment may be supported by affidavits, so long as those affidavits "set out facts that would be admissible into evidence." Fed. R. Civ. P. 56(c) and (e)(1). As the Platt Declaration sets out facts that would be admissible into evidence, Roxane has no basis to dispute statements of fact on the ground that they rely on Mr. Platt's affidavit and opinions. *See*, *e.g.*, *Iacobelli Const., Inc. v. County of Monroe*, 32 F.3d 19, 25 (2d Cir. 1994) ("An affidavit stating the facts upon which the expert's opinion is based satisfies rule 56(e) even if the data supporting the facts is not attached.")

55. On or about December 1, 1997, Roxane again lowered its WAC for generic ipratropium bromide from $25.50 to $20.50. (Fauci Exhibit 47) Again, Roxane did not lower its AWP. (Fauci Exhibit 3 (Platt Decl.), Summary A1) Roxane did not report this WAC reduction toFirst Data Bank, as Roxane decided to stop reporting WACs to the pricing compendia in or around December 1997. (*See infra* ¶¶ 123-125; *see also* Fauci Exhibit 22 (9/30/2005 Leslie Paoletti Dep.), at 85:6 - 85:21; Fauci Exhibit 48) As a result, the $25.50 WAC continued to be published in First Data Bank. (Fauci Ex. 3 (Platt Decl.), at Summary A1)

Roxane's Response: Undisputed that Roxane lowered its WAC price for its IB UDV 2.5 ml 25s on or around December 1, 1997 from $25.50 to $20.50. Undisputed that consistent with its standard practice and practice in the industry, it did not lower its AWP at that time. (Roxane SOF at ¶ 106) Roxane, however, objects to Plaintiff's alleged fact because it is not supported by citations to the record as required by Local Rule 56.1. *See O'Brien*, 440 F. Supp. 2d at 5 n.1 (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule 56.1). The Government cites to an expert declaration in support of this alleged fact, but the expert declaration is unsupported by citations to the record. (Fauci Ex. 3, Declaration of Platt (filed under seal) at Summary A1) Disputed that "Roxane did not report this WAC reduction to First Data Bank, as Roxane decided to stop reporting WACs to the pricing compendia in or around December 1997" and that "[a]s a result, the $25.50 WAC continued to be published in First Data Bank." The Government's proferred evidence does not support these facts. First, paragraph 123-125, *infra*, and Ms. Paoletti's deposition testimony discusses only generally that in December 1997/early 1998 Roxane decided to and stopped reporting WACs on its multi-source products; neither gives a specific date when Roxane stopped reporting WACs or supports that the specific WAC change for ipratropium bromide referenced in this paragraph was not reported. Indeed, Fauci Exhibit 48 (cited both here and in paragraphs 123-125) dated December 8th, 1997 implies that as of that time, Roxane had not yet made a final decision regarding whether to stop reporting WACs. (Fauci Ex. 48, 12/8/97 Mayhew Email to Waterer ("*So if we decide to not supply them with WAC* for price increases they will use old pricing.") (emphasis added)) Roxane also incorporates by reference its responses to paragraphs 123-125, *infra*. Second, as stated above, the expert declaration cited by the Government is not supported by citations to the records as required by Local Rule 56.1.

UNITED STATES' REPLY: Roxane suggests that the United States has not proffered evidence establishing that Roxane's prior WAC of $25.50 continued to be published in First Data Bank after Roxane had reduced its WAC to $20.50. The Platt Affidavit shows that Roxane's old WAC of $25.50 continued to be published in First Data Bank through at least the end of 1998, even though Roxane reduced the WAC to $20.50 in December 1997. (Fauci Exhibit 3 (Platt

Decl.), at Summary A1; Fauci Exhibit 134 (Dew Decl.), at ¶¶ 17-18) Roxane offers no evidence to the contrary. Further answering, *see supra* United States' Reply to Roxane's Response to Paragraph 55.

56. From 1996 through at least 2001, Roxane offered regular price reductions on generic ipratropium bromide, but Roxane never lowered the AWP. (Fauci Exhibit 3 (Platt Decl.), at Summary A1) Roxane's letters to customers announcing price reductions for its ipratropium bromide products frequently compared the offered contract price to the AWP. (*See*, *e.g.*, Fauci Ex. 49; Fauci Ex. 50; Fauci Ex. 51; Fauci Ex. 52)

Roxane's Response: Disputed that "[f]rom 1996 through at least 2001, Roxane offered regular price reductions on generic ipratropium bromide" as the Government's proffered evidence does not support this alleged fact. The expert declaration the Government references is not supported by citations to the record as required by Local Rule 56.1. (Fauci Ex. 3, Declaration of Platt (filed under seal) at Summary A1) *See O'Brien*, 440 Supp. 2d at 5 n.1 (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule 56.1). Roxane also disputes that the "contract prices" listed in the Government's expert declaration accurately reflect Roxane's indirect contract prices to its customers for ipratropium bromide. (*See* Roxane's Resp. to US Roxane SOF at ¶¶ 26, 28, *supra*) Undisputed that Roxane reduced prices at various times between 1996 through 2001 to certain customers on the three Roxane ipratropium bromide NDCs at issue and that consistent with its practice and practice in the industry, Roxane did not change the AWP that was set at the launch of each NDC at those times. (Roxane SOF at ¶ 106) Disputed that "Roxane's letters to customers announcing price reductions for its ipratropium bromide products frequently compared the offered contract price to the AWP." The Government's proferred evidence does not support this alleged fact. First, Roxane's contract prices vary by customer and can change on a daily basis. (*See, e.g.,* Tab 276, 5/9/07 Waterer Dep. 337 ("Contract price is fluid. It changes depending on what stage the product is in and the competitive environment. It can change daily, hourly, weekly, or stay stable for years. So it's very individual.")) The Government points only to handful of contract price changes with five customers for a six year period. (*See* Fauci Exs. 49-52, various letters to customers announcing new contract prices) Moreover, the several price announcements referenced do not contain any type of "comparison" between the contract price and the AWP, they simply list both on the page, as this was information typically requested by the customer. (Tab 283, Response to Interrogatory No. 11, 3/12/08 Defendant Boehringer Ingelheim Roxane's, Inc.'s Answers and Objections to Plaintiff's Second Set of Interrogatories (*Illinois v. Abbott Labs., et. al*))

UNITED STATES' REPLY: Inexplicably, Roxane disputes that its letters to customers frequently compared the offered contract price to the AWP, on the ground that the United States'

proffered evidence consists of only "a handful of price changes with five customers for a six year period." In an effort to minimize the number of documents submitted to the Court, the United States submitted nine such letters, each of which listed the contract price next to the AWP. (*See*, *e.g.*, Fauci Exhibit 49; Fauci Exhibit 50; Fauci Exhibit 51; Fauci Exhibit 52). A great many more such letters have been produced by Roxane, and the United States will submit them if the Court wishes. Further answering, *see supra* the United States' replies to Roxane's responses to Paragraphs 26 and 28.

57. For example, on or about July 20, 1999, Debbie Kutner (a National Account Manager) sent a Price Adjustment Request ("PAR") to the contracts department. The PAR noted that a customer had received a proposal from Dey Laboratories to supply ipratopium bromide at $11.00. Ms. Kutner recommended that Roxane "meet the competition and stay market competitive." (Fauci Exhibit 53)

Roxane's Response: Undisputed that Fauci Exhibit 53 indicates that Ms. Kutner sent a Price Adjustment Request on July 20, 1999 noting that one customer had received a proposal from "Dey Labs promoting Ipratroprium 25's for $11.00" and that Ms. Kutner wanted to "meet the competition and stay market competitive." The Government's quotations are selective and incomplete; the document in its entirety is the best evidence of its content. Roxane disputes that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co*., 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

58. Handwritten notes on the PAR state "Pls. create AWP. price red. doc 8-1-99 _ 5-31-00." (*Id*.) The following day (July 21, 1999) Roxane sent a letter notifying the customer of the price reduction and listing the new, reduced price to the customer next to the AWP. (Fauci Exhibit 54)

Roxane's Response: Undisputed that handwritten notes on Fauci Exhibit 53 appear to state what the Government has quoted, but no witness has confirmed what the phrase means or who wrote the note. (*See* Tab 241, 12/9/08 Kutner Dep. 65-66) Undisputed that on July 21, 1999, Roxane sent a letter to the customer notifying them of a new price for ipratropium 25s of $18.65 (exclusive of market-share driven rebates) and that the AWP was also listed. (Fauci Ex. 54, 7/21/99 Storck Letter to Vilardi) Roxane disputes that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1

(requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co*., 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

59. On October 2, 1998, Judy Waterer (then Roxane's Assistant Director of Multi–Source Marketing) sent an email identifying the AWPs and WACs for Roxane and Dey Laboratories' ipratropium bromide products. Ms. Waterer cautioned that "[t]hese are published prices only. The AWP and WAC have little relation to actual net selling price after chargebacks, discounts, rebates, etc." (Fauci Exhibit 55) (emphasis in original)

Roxane's Response: Undisputed that in Fauci Exhibit 55, 10/2/98 Waterer Email to Grinton, Ms. Waterer listed AWPs and WACs for Roxane and Dey ipratropium bromide products and stated what the Government has quoted. Ms. Waterer's comments are consistent with Roxane's understanding and the understanding in the industry that AWPs were not intended to represent an actual average of wholesale prices to customers. (Roxane SOF at ¶¶ 99-101)

B. Roxane Raised the AWPs for Several Products Following Launch, Even When Sales Prices To Customers Were Not Increasing

1. Hydromorphone

60. In or around July 1998, Roxane determined that the AWPs for its hydromorphone 2 mg and 4 mg tablets (NDCs 00054-4392-25 and 00054-4394-25) were lower than those of competitors. (Fauci Exhibit 56, at RLI-AWP-00316337) According to a July 1998 monthly report, Roxane was losing market share on this product as a result of its "AWP being positioned incorrectly." (*Id*.) Roxane also determined that because the product was "still not MAC'd," Roxane's ability to sell the product was being "negatively impacted." (*Id*.)

Roxane's Response: Undisputed that the document cited by the Government contains the facts and quotations referenced. The Government's characterizations and quotations, however are selective and incomplete; the document in its entirety is the best evidence of its content. Disputed that the facts alleged in paragraph 60 are material to the Government's motion for summary judgment or its claims against Roxane as they did not occur during the timeframe relevant to theGovernment's claims. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to hydromorphone. (United States' Consolidated Memorandum of Law in Support of

Cross-Motion for Partial Summary Judgment and in Opposition to the Roxane Defendants' Motion for Summary Judgment at 3, n.3)

UNITED STATES' REPLY: Roxane's attempt to deny the materiality of the evidence against it is futile. The document referenced in Paragraph 60 relates to NDCs which are at issue in this litigation. The document explains the rationale behind Roxane's August 1998 decision to raise the AWP for these products. The AWPs set in August 1998 were the AWPs Roxane reported throughout the relevant timeframe. In a case about inflated AWPs, evidence of why Roxane set AWPs as it did is of central importance.

61. A proposed AWP increase for hydromorphone was circulated in August 1998. (*Id; see also* Fauci Exhibit 57) The "AWP Increase Proposal" recommended raising the AWP on the 100 tablet (4 mg) hydromorphone product from $47.53 to $61.31. (Fauci Exhibit 57) The proposed AWP was slightly higher than the AWPs of two generic competitors, and significantly higher than the AWPs of the remaining competitors. (*Id*.) The proposal also noted that $61.31 was "the [] maximum AWP Roxane could assign based on brand AWP." (*Id*.)

Roxane's Response: Undisputed that a proposed AWP increase for hydromorphone was routed for approval in or around August 1998 that recommended raising the AWP on the 100 tablet (4 mg) hydromorphone product from $47.53 to $61.31. Undisputed that Fauci Exhibit 57, the "AWP Increase Proposal," appears to indicate that the AWP of $61.31 for the 100 tablet (4 mg) hydromorphone product was higher than the AWPs of the other generic competitors listed, although only 5-6 cents higher than Endo's AWPs and 23-36 cents higher than Mallinkrodt's AWPs. Roxane objects to the characterizations by the Government that the proposed AWP was either "slightly" or "significantly" higher than the AWPs of the competitors on the grounds that such descriptions are subjective, argumentative and not fact. Disputed that the proposal noted that $61.31 was the "maximum AWP Roxane could assign based on brand AWP." This alleged fact is not supported by the Government's proffered evidence, Fauci Exhibit 57. Rather, in Fauci Exhibit 57 it is noted that $61.31 is "[a]pproximately 5% less than the maximum AWP Roxane could assign based on brand AWP."

Disputed that the facts alleged in paragraph 61 are material to the Government's motion for summary judgment or its claims against Roxane as they relate to events that occurred outside the timeframe relevant to the Government's claims. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.,* 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's

immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to hydromorphone. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 60.

62. On or about August 19, 1998, Roxane issued a product announcement, comparing the old AWPs to the new AWPs for its hydromorphone products. (Fauci Exhibit 58) The new AWP for the 100 tablet (4 mg) product was $61.31. (*Id.*)

Roxane's Response: Undisputed that Fauci Exhibit 58 is a product announcement, listing the old AWP and the new AWP, with the new AWP listed as $61.31 for Roxane's 100 tablet (4 mg) hydromorphone product. Roxane disputes and objects to the Government's alleged fact that this product announcement was "issued" or circulated. The Government's proffered evidence does not support this alleged fact. Fauci Exhibit 58, by itself, does not indicate whether this product announcement is a draft or final version, and/or whether this product announcement was ever distributed or circulated. Disputed that the facts alleged in paragraph 62 are material to the Government's motion for summary judgment or its claims against Roxane as they relate to events that occurred outside the timeframe relevant to the Government's claims. *See* Local Rule56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to hydromorphone. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 60.

63. Letters sent to customers announcing reductions in contract prices for these products listed the reduced prices along with the corresponding AWP. For example, a June 16, 1999 letter offered Cardinal a price of $14.70 on the 100 tablet (4 mg) bottle, compared to the AWP of $61.31. (Fauci Exhibit 59)

Roxane's Response: Undisputed that a June 16, 1999 letter offered Cardinal a price of $14.70/C on the 100 (4 mg) bottle of hydromorphone. (Fauci Ex. 59, 6/16/99 Self Letter to Bilacic) Undisputed that this same letter also listed the AWP of $61.31 for the 100 tablet (4 mg) bottle. Disputed that Roxane sent multiple "letters" to multiple "customers" announcing reductions in contract prices for these products along with the corresponding AWP as that

alleged fact is not supported by the Government's citations to the record, as is required by Local Rule 56.1. *See O'Brien*, 440 F. Supp. 2d at 5 n.1 (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule 56.1). The Government only cites to one letter sent to one customer. In addition, Roxane objects to and disputes the characterization that the letter attached as Fauci Exhibit 59 "compares" the contract price to the AWP when the letter merely includes both the contract price and AWP without any indication that the two values should be compared to each other. In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to hydromorphone. (US Cons. Memo re Roxane at 13, n.11) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.,* 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

UNITED STATES' REPLY: Roxane disputes that it sent multiple letters to customers announcing reductions in contract prices along with the corresponding AWP, on the ground that the United States "only cites to one letter sent to one customer." The documents produced by Roxane to the United States contain numerous examples of such letters; three such letters are found at Fauci Reply Exhibit 185.

2. Azathioprine

64. On or about February 16, 1996, Roxane received approval to launch 50 mg azathioprine tablets (NDCs 00054-4084-25). (Fauci Exhibit 60) Promotional materials described Roxane's azathioprine product as the first generic form of Imuran, a brand drug. (Fauci Exhibit 61)

Roxane's Response: Roxane does not dispute that it launched 50 mg azathioprine tablets (NDC 00054-4084-25), the first generic form of the brand Imuran, in February 1996. However, Roxane disputes the materiality of this fact to the Government's claims as it did not occur during the timeframe relevant to the Government's claims, which does not begin until 1999 for azathioprine. Roxane also disputes the materiality of this fact to the Government's Medicare claims because the United States does not intend to pursue damages for Medicare claims relating to azathioprine. (*See* US Cons. Memo re Roxane at 3, n.3) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.,* 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

UNITED STATES' REPLY: *See infra* United States' Reply to Roxane's Response to Paragraph 65.

65. Roxane originally set the AWP and the WAC for a bottle of 100 (50 mg) azathioprine tablets at $111.24 and $77.90, respectively. (*Id.*) Roxane's announcements for these products listed the AWPs and WACs and encouraged customers to "[c]ompare acquisition cost and AWP." (*Id.*)

Roxane's Response: Undisputed that the launch AWP for azathioprine tablets was $111.29. Undisputed that the WAC for a bottle of 100 (50 mg) azathioprine tablets was set at $77.90 at launch. Undisputed that Roxane's announcement contained the quoted language. The Government's quotation however is selective, incomplete and misleading; the document in its entirety is the best evidence of its contents. Specifically, the quote is in the context of how Roxane's product relates to the brand, Imuran, and the entire sentence is "Cost Savings – Compare acquisition cost and AWP." (Fauci Ex. 61, 2/16/96 New Product Announcement re Azathioprine) Taking the entire quote in context, it conveys that there is a cost savings to the customer as between the brand, Imuran, and Roxane's generic azathioprine. Moreover, the Government does not cite to any evidence that this product announcement was ever actually sent to or seen by any potential customers.

Disputed that this fact is material to the Government's claims against Roxane as it did not occur during the timeframe relevant to the Government's claims, which does not begin until 1999 for azathioprine. Disputed that this fact is material to the Government's Medicare claims against Roxane because the United States does not intend to pursue damages for Medicare claims relating to azathioprine. (*See* US Cons. Memo re Roxane at 3, n. 3) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.,* 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

UNITED STATES' REPLY: Roxane's attempt to deny the materiality of the evidence against it is unsupported. The document referenced in Paragraph 65 relates to NDCs which are at issue in this litigation. Evidence of Roxane's practice of encouraging customers to "[c]ompare acquisition cost and AWP" is plainly material to the United States' allegations in this case.

66. A February 19, 1996 Marketing Memo instructed Roxane's sales force to "go back over the Medicare selling message" when preparing sales calls.

Simply stated, if a pharmacy buys Roxane

> azathioprine at $77 the Medicare reimbursement will represent a $40 profit ($117-$77 WAC) vs. $14 profit with Imuran ($117-$103 WAC). Remember the Medicare reimbursement code KO119 is for azathioprine 50 mg tablets REGARDLESS OF MANUFACTURER!

(Fauci Exhibit 62, 2/16/96 Dusek Marketing Memo) (emphasis in original)

Roxane's Response: Disputed that this fact is material to the Government's claims against Roxane as it did not occur during the timeframe relevant to the Government's claims, which does not begin until 1999 for azathioprine. Disputed that this fact is material to the Government's Medicare claims because the United States does not intend to pursue damages for Medicare claims relating to azathioprine. (*See* US Cons. Memo re Roxane at 3, n.3) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.,* 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

Undisputed that the document contains the quoted language. The Government's quotations, however, are selective and misleading; the document in its entirety is the best evidence of its content. Roxane set the AWP for azathioprine at $111.29, 10% below the Imuran brand AWP. (Fauci Ex. 61, 2/16/96 New Product Announcement re Azathioprine; Tab 277, 7/24/07 Waterer Dep. 775-76; Fauci Ex. 63, 11/25/96 Waterer Memo to Tupa at ROX028-4799) Roxane understood this to be the standard industry practice. (Roxane SOF at ¶ 99) The memo recognizes that individual manufacturer's AWPs are irrelevant in the Medicare context because providers received the same Medicare reimbursement regardless of which manufacturer's product they purchased. Therefore there is no incentive for manufacturers to "market the spread" based on higher AWP prices. Rather, the incentive is to offer lower contract/WAC prices. (Tab 254, 5/12/09 Scott Morton Dep. 184-86; Tab 255, Scott Morton Dep. 321-22, 326; Tab 279, 5/21/09 Williams Dep. 280-81) In the case of azathioprine, Roxane set its prices to encourage conversion from the brand to its generic (Tab 253, 1/8/09 Russillo Dep. 131), a goal that the CMS itself just recently stated justified AWP to acquisition costs spreads as high as 73%:

> The Report also found that the percentage differences between Part D payments and drug acquisition costs were more than nine times higher for generic drugs than for brand-name drugs. Clinically appropriate generic prescribing is one of the key ways in which the Part D program is able to provide high quality coverage at a reasonable cost to both beneficiaries and the government. We fully encourage the use of generic drugs since their use provides good value to both the beneficiary and the taxpayer, and *we note that incentives are aligned to encourage promotion of generics by community pharmacies*.

(Tab 126, January 2008 OIG Report at 6 and pg. 1 of App. G (emphasis added))

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 50 (explaining that the report referenced at Tab 126 does *not* provide evidence to support a finding that CMS ever approved of a drug manufacturers' reporting inflated AWPs for any drugs reimbursed by Medicare or Medicaid; the report referenced by Roxane relates *only* to the Medicare Part D Program, which does *not* involve reimbursement of claims by the government).

67. In or around December 1996, Roxane increased prices the AWP and WAC for the 100 tablet bottle of azathioprine to $116.74 and $83.35, respectively. According to "a price increase analysis" sent by Ms. Waterer to Mr. Tupa on November 25, 1996, Roxane "kept the dollar amount of the spread as it was before the price change, so customers will still make the same amount per bottle." (Fauci Exhibit 63)

Roxane's Response: Disputed that this fact is material to the Government's claims against Roxane as the changes did not occur during the timeframe relevant to the Government's claims, which does not begin until 1999 for azathioprine. Disputed that this fact is material to the Government's Medicare claims against Roxane because the United States does not intend to pursue damages for Medicare claims relating to azathioprine. (*See* US Cons. Memo re Roxane at 3, n.3) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.,* 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

Undisputed that the document contains the quoted language. The Government's quotation, however, is selective and incomplete as it omits the fact that Roxane's price increase was in response to a "large price increase in [the brand] bottles of 100"; the document in its entirety is the best evidence of its content. In 1996, Roxane was the sole source in the market for generic azathioprine, and thus its only competition was from the brand product, Imuran. Ms. Waterer explained that "it was common for us when you're a sole source generic to tie your AWP to the brand's AWP. As a sole source generic, if the brand increased the price, we chose to go in tandem and increase ours as well. So we were following the lead of the brand." (Tab 277, 7/24/07 Waterer Dep. 771-72) Having the market's sole source generic for Imuran provided Roxane the "opportunity when the brand increases the price because of the competitive dynamics to increase the price in tandem with the brand and still be offering a significant discount to the end use customer." (*Id.*) Roxane increased both the AWP and the WAC for azathioprine, keeping

the "dollar amount of the spread as it was before the price change." (Fauci Ex. 63, 11/25/96 Waterer Memo to Tupa at ROX028-4797)

UNITED STATES' REPLY: Roxane's attempt to deny the materiality of the evidence against it is unsupported. The document referenced in Paragraph 67 relates to NDCs which are at issue in this litigation. Evidence of why Roxane set AWPs as it did for the Subject Drugs is of central importance to this litigation.

68. In or around December 1998, Roxane became aware that its competitor had raised the AWP for Imuran, the brand equivalent for azathioprine. (Fauci Exhibit 64) According to a "National Accounts Monthly Report" dated December 1998, customers wanted Roxane "to raise our AWP but not our price." (*Id*.) Mr. Sykora (then Director of National Accounts) wrote that this was:

> an opportunity to overcome two of the most common complaints heard for the lower than usual generic substitution rate for aza - too small a spread between awp and price on aza and too small a spread between imuran wac and aza wac[.]

(*Id*., at BOEH01046914; Fauci Exhibit 65 (12/12/2008 Colin Carr-Hall Dep.), at 206:16 – 208:14) Roxane employees recognized that raising the AWP or lowering the price to customers would increase the "spread" and thereby make azathiprine more profitable to customers. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 142:2 - 145:17; Fauci Exhibit 66 (12/9/2008 Deborah Kutner Dep.), at 111:8 - 113:2, 116:10 - 119:10; Fauci Exhibit 27 (5/9/2007 Judith Waterer 30(b)(6) Dep.), at 162:1 - 163:1)

Roxane's Response: Roxane disputes that this is fact material to the Government's claims against Roxane as the changes did not occur during the timeframe relevant to the Government's claims, which does not begin until 1999 for azathioprine. Disputed that azathioprine price changes are material to the Government's Medicare claims against Roxane because the United States does not intend to pursue damages for Medicare claims relating to azathioprine. (*See* US Cons. Memo re Roxane at 3, n.3) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.,* 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

Undisputed that the December 1998 "National Accounts Monthly Report" contains the

language quoted. Undisputed that Roxane became aware that its competitor had raised the AWP for Imuran around December 1998. The Government's quotations, however, are selective, incomplete and misleading; the document in its entirety is the best evidence of its content. Roxane did not raise its azathioprine AWPs in response to Imuran's December 1998 increase. Because it had the only generic product on the market, Roxane's goal was to provide incentives for customers to switch from the brand Imuran to its generic azathioprine (Tab 253, 1/8/09 Russillo Dep. 131), a goal that the CMS itself just recently stated justified AWP to acquisition costs spreads as high as 73%:

> The Report also found that the percentage differences between Part D payments and drug acquisition costs were more than nine times higher for generic drugs than for brand-name drugs. Clinically appropriate generic prescribing is one of the key ways in which the Part D program is able to provide high quality coverage at a reasonable cost to both beneficiaries and the government. We fully encourage the use of generic drugs since their use provides good value to both the beneficiary and the taxpayer, and *we note that incentives are aligned to encourage promotion of generics by community pharmacies*.

(Tab 126, Jan. 2008 OIG Report at 6 and pg. 1 of App. G (emphasis added))

Roxane, however, heard complaints from customers and experienced a lower than usual generic substitution rate for azathioprine. (Fauci Ex. 64, December 1998 National Accounts Monthly Report at BOEH01046914) As Mr. Russillo testified:

> When we set our AWP, it was normally set at 10 percent underneath the AWP of the brand. And then contract pricing was based on that AWP. As I mentioned earlier, when you put those all into a formula, the idea was the pharmacy should be incented [sic] to dispense our product. . . over the brand. As AWP increased for the brand, and the generic did not follow suit, we would not see that incentive.

(Tab 253, 1/8/09 Russillo Dep. 131) Contrary to the Government's implication, although customers wanted Roxane to raise its AWP in December 1998, Roxane did not raise its AWP again until late 1999, after generic competitors entered the market and based their AWPs on the higher brand price. (Tab 277, 7/24/07 Waterer Dep. 806-07; Tab 253, 1/8/09 Russillo Dep. 294-95)

Roxane disputes the Government's characterization of the proffered evidence in sentence four. Although raising an AWP or decreasing a contract price could make azathioprine more profitable for customers, Roxane's focus was on ensuring that its product remained equally profitable so as to not be competitively disadvantaged. (Fauci Ex. 27, 5/9/07 Waterer Dep. 162; Fauci Ex. 13, 1/8/09 Russillo Dep. 142-44)

UNITED STATES' REPLY: Roxane's attempt to deny the materiality of the evidence

against it is futile. The document referenced in Paragraph 68 relates to NDCs which are at issue in this litigation. Evidence of how Roxane set AWPs as it did for the Subject Drugs is of central importance to this litigation. Further answering, *see supra* United States' Reply to Roxane's Response to Paragraph 50 (explaining that the report referenced at Tab 126 does *not* provide evidence to support a finding that CMS ever approved of a drug manufacturers' reporting inflated AWPs for any drugs reimbursed by Medicare or Medicaid; the report referenced by Roxane relates *only* to the Medicare Part D Program, which does *not* involve reimbursement of claims by the government).

69. Roxane offered regular price reductions to customers for azathioprine throughout 1999. Letters notifying customers of these price reductions frequently compared the offered price to the AWP. (*See*, *e.g.*, Fauci Exhibit 67; Fauci Exhibit 68; Fauci Exhibit 69; Fauci Exhibit 70)

Roxane's Response: Disputed. The Government's proffered evidence does not support the alleged fact that Roxane offered "regular price reductions. . . throughout 1999." The Government's exhibits are four letters to separate customers offering price reductions, and the letters span a one-month timeframe in 1999, from August 12 to September 7. Roxane notes that these price reductions occurred after a second generic entered the market in competition with Roxane's azathioprine. (Tab 277, 7/24/07 Waterer Dep. 807) Roxane also disputes the characterization that the letters "frequently compared the offered price to the AWP," where the letters merely list both prices. Disputed that this fact is material to the Government's Medicare claims against Roxane because the United States does not intend to pursue damages for Medicare claims relating to azathioprine. (*See* US Cons. Memo re Roxane at 3, n. 3) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.,* 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

UNITED STATES' REPLY: Inexplicably, Roxane disputes that its letters to customers frequently compared the offered contract price to the AWP, on the ground that the United States' proffered evidence consists of only four such letters. Each letter shows that Roxane listed the AWP next to the offered contract price. (*See*, *e.g.*, Fauci Exhibit 67; Fauci Exhibit 68; Fauci

Exhibit 69; Fauci Exhibit 70) A great many more such letters have been produced by Roxane, and the United States will submit them if the Court wishes.

70. On or about September 10, 1999, Ms. Waterer sent a telefax to Thomas Russillo (then Roxane's Director of Multi-Source Marketing) containing an "azathioprine price analysis." (Fauci Exhibit 71) The analysis showed that Roxane's AWPs for its azathioprine products were lower than those of competitors. The analysis proposed raising Roxane's AWPs to as least as high as those of competitors. (*Id.*; Fauci Exhibit 72 (7/24/2007 Judith Waterer Dep.), at 811:22 - 813:1)

Roxane's Response: Undisputed that Ms. Waterer sent a telefax to Mr. Russillo containing an "azathioprine price analysis" and that the analysis showed that Roxane's AWPs were lower than its competitors' AWPs and proposed raising Roxane's AWPs to be consistent with its competitors. The document and testimony cited, however, is selective and incomplete; the document and testimony in their entirety are the best evidence of their content. In 1999, Roxane's AWP was lower than that of its new generic competitors because it was set at 10% below the 1996 brand AWP, and had not been raised in concert with the brand. When new generic competitors entered the market in 1999 they set their AWPs at 10% below the 1999 brand AWP, which was higher. (Tab 253, 1/8/09 Russillo Dep. 140-41) As Mr. Russillo explained:

> What this tells me is Roxane was the first azathioprine in 1996. It was set – its AWP was set at the time. In subsequent years, Glaxo raised their price. When Faro later introduced their generic, they did the same thing. They took a 10 percent from a higher AWP. We were competitively disadvantaged, and we were trying to catch up.

(*Id.*) The azathioprine price analysis, prompted by customer complaints, shows that Roxane's proposed AWP change was to set the AWP at 10% less than the current brand AWP consistent with Roxane's practice and practice in the industry. (Tab 277, 7/24/07 Waterer Dep. 806-07("…Geneva launched in June of 1999…our AWP was lower than Geneva's. Customers were complaining about it, so we had to bring our AWP in line with the then current market."); Tab 253, 1/8/09 Russillo Dep. 294-95 ("We saw that Geneva had a higher AWP than we did. We saw that Faro's AWP, Glaxo's Imuran product, had gone up over the years. We were no longer competitive…we took that price and took 10 percent off. And I'll bet the math works out that 131.08 is 10 percent less than 145.64.)) Ms. Waterer testified that after changing the AWP, it was "within pennies" of its competitor Geneva's AWP. (Fauci Ex. 72, 7/24/07 Waterer Dep. 812)

Disputed that this fact is material to the Government's Medicare claims against Roxane because the United States does not intend to pursue damages for Medicare claims relating to azathioprine. (*See* US Cons. Memo re Roxane at 3, n. 3) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the

moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.,* 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

71. Also on September 10, 1999, Anthony Tavolaro (then, a National Accounts Manager) emailed Ms. Waterer asking for an "update" on the proposed AWP change for azathioprine. Mr. Tavolaro noted that a mail-order pharmacy was asking Roxane "to raise the AWP or lower our price to meet the spread." (Fauci Exhibit 180) Later that day, Mr. Russillo approved raising the AWPs for Roxane's azathioprine from $116.74 to $131.08. (*Id.*; Fauci Exhibit 73)

Roxane's Response: Undisputed that the document contains the quotations cited and that Mr. Russillo approved raising Roxane's azathioprine AWPs as noted. The quotations, however, are selective, incomplete and misleading; the document in its entirety is the best evidence of its content. In 1999, Roxane's AWP was lower than that of its new generic competitors because it was set at 10% below the 1996 brand AWP, and had not been raised in concert with the brand. When new generic competitors entered the market in June 1999, they set their AWPs at 10% below the 1998 brand AWP, which was higher. (Tab 253, 1/8/09 Russillo Dep. 140-41; Tab 277, 7/24/07 Waterer Dep. 806-07) As Mr. Russillo explained:

> What this tells me is Roxane was the first azathioprine in 1996. It was set – its AWP was set at the time. In subsequent years, Glaxo raised their price. When Faro later introduced their generic, they did the same thing. They took a 10 percent from a higher AWP. We were competitively disadvantaged, and we were trying to catch up.

(Tab 253, 1/8/09 Russillo Dep. 140-41) Prompted by customer complaints, Roxane analyzed the situation and proposed an AWP change to set the AWP at 10% less than the brand AWP consistent with its competitors. (Tab 277, 7/24/07 Waterer Dep. 806-07 ("…Geneva launched in June of 1999…our AWP was lower than Geneva's. Customers were complaining about it, so we had to bring our AWP in line with the then current market."); Tab 253, 1/8/09 Russillo Dep. 294-95 ("We saw that Geneva had a higher AWP than we did. We saw that Faro's AWP, Glaxo's Imuran product, had gone up over the years. We were no longer competitive…we took that price and took 10 percent off. And I'll bet the math works out that 131.08 is 10 percent less than 145.64.")) Ms. Waterer testified that after changing the AWP, it was "within pennies" of its competitor Geneva's AWP. (Tab 277, 7/24/2007 Waterer Dep. 812)

Disputed that this fact is material to the Government's Medicare claims against Roxane because the United States does not intend to pursue damages for Medicare claims relating to azathioprine. (*See* US Cons. Memo re Roxane at 3, n. 3) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.,* 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary

judgment movant's immaterial facts).

72. Mr. Russillo testified that he approved raising the AWPs for Roxane's azathioprine products to match competitors' AWPs, which had increased over time. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 293:18 - 294:17) Mr. Russillo also testified that increasing the AWPs provided a competitive advantage for Roxane. (*Id*.)

Roxane's Response: Undisputed that Mr. Russillo testified to the alleged facts, but the Government's characterizations and quotations are selective, incomplete and misleading. In 1999, Roxane's AWP was lower than that of its new generic competitors because it was set at 10% below the 1996 brand AWP, and had not been raised since. Roxane's new generic competitors set their AWPs at 10% below the 1998 brand AWP, which was higher. (Fauci Ex. 13, 1/8/09 Russillo Dep. 140-41) As Mr. Russillo explained:

> What this tells me is Roxane was the first azathioprine in 1996. It was set – its AWP was set at the time. In subsequent years, Glaxo raised their price. When Faro later introduced their generic, they did the same thing. They took a 10 percent from a higher AWP. We were *competitively disadvantaged*, and we were trying to catch up.

(*Id*. (emphasis added)) Prompted by customer complaints, Roxane analyzed the situation and proposed an AWP change to set the AWP at 10% less than the brand AWP consistent with its competitors. (Tab 277, 7/24/07 Waterer Dep. 806-07 ("…Geneva launched in June of 1999…our AWP was lower than Geneva's. Customers were complaining about it, so we had to bring our AWP in line with the then current market."); Fauci Ex. 13, 1/8/09 Russillo Dep. 294-95 ("We saw that Geneva had a higher AWP than we did. We saw that Faro's AWP, Glaxo's Imuran product, had gone up over the years. We were no longer competitive…we took that price and took 10 percent off. And I'll bet the math works out that 131.08 is 10 percent less than 145.64.")) Ms. Waterer testified that after changing the AWP, it was "within pennies" of its competitor Geneva's AWP. (Tab 277, 7/24/2007 Waterer Dep. 812)

Disputed that this fact is material to the Government's Medicare claims against Roxane because the United States does not intend to pursue damages for Medicare claims relating to azathioprine. (*See* US Cons. Memo re Roxane at 3, n. 3) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.,* 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

73. Subsequently, in late 1999 and 2000, Roxane continued to offer price reductions to its customers on azathioprine. Letters notifying customers of the price change compared the new offered price to Roxane's increased AWP. (*See e.g.*, Fauci

Exhibit 74; Fauci Exhibit 75; *compare* Fauci Exhibit 75 *with* Fauci Exhibit 67)

Roxane's Response: Disputed. The Government's proffered evidence does not support the alleged fact that "in late 1999 and 2000, Roxane continued to offer price reductions to its customers on azathioprine." Fauci Exhibits 74 and 75 show price reduction offers to only two customers, one in September 1999, and one in February of 2000. Roxane also disputes the characterization that the letters "compared the new offered price to Roxane's increased AWP," where the letters merely list both prices.

Disputed that this fact is material to the Government's Medicare claims against Roxane because the United States does not intend to pursue damages for Medicare claims relating to azathioprine. (*See* US Cons. Memo re Roxane at 3, n. 3) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.,* 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

UNITED STATES' REPLY: Inexplicably, Roxane disputes that its letters to customers frequently compared the offered contract price to the AWP, on the ground that the United States' proffered evidence consists of letters sent to only two customers. A great many more such letters have been produced by Roxane, and the United States will submit them if the Court wishes.

3. Furosemide

74. In April 2000, several customers complained to Roxane that the AWPs for its furosemide products were "too low." (*See, e.g.*, Fauci Exhibit 76; Fauci Exhibit 76A; Fauci Exhibit 76B)

Roxane's Response: Undisputed. Disputed that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. (Roxane SOF at ¶ 120) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: Roxane's attempt to deny the materiality of the evidence against it is futile. Although there were FULs in place for "many of the furosemide NDCs at issue[,]" Roxane still caused harm to the Medicaid program by reporting inflated AWPs for its furosemide products. Nearly all state Medicaid programs utilized a "lower of" reimbursement methodology, paying the lesser of various price points including AWP and FULs. *See* United Staets Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants ("US-C-SF"), ¶ 29. Therefore, if Roxane reported lower AWPs for its furosemide drugs, Medicaid would have paid less in reimbursement, at least where Roxane's reported AWPs were lower than the FUL.

75. For example, on or about April 14, 2000, Mr. Sykora sent an email to Ms. Waterer notifying her that Caremark "would like to give" Roxane its furosemide business "except our AWP was far too low for it to be profitable for them." (Fauci Exhibit 76) Mr. Sykora noted that Roxane's AWP on one furosemide product was $45.25, while its competitors' AWPs were in excess of $140.00. (*Id.*) Mr. Sykora stated that "[t]his is certainly a hindrance to retail customers wanting to use our product. It would appear that an adjustment to the mid-140's [sic] is justified." (*Id.*)

Roxane's Response: Undisputed that the document contains the quoted language. The Government's quotations, however, are selective and incomplete; the document in its entirety is the best evidence of its content. Disputed that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. (Roxane SOF at ¶ 120) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 74.

76. Employees in Roxane's marketing department testified that Roxane was unable to sell its furosemide products during this time frame due to the fact that Roxane's AWPs were lower than those of competitors. (*See, e.g.*, Fauci Exhibit 77 (7/26/2007 Leslie Paoletti Dep.), at 77:1 0 - 80:8) As a result, Roxane considered discontinuing the product. (*See, e.g.*, Fauci Exhibit 78 (11/10/2004 Leslie Paoletti Dep.), at 195:8 - 196:1) According to Ms. Waterer, Roxane needed to "either discontinue the product or act like a competent marketer and do what everybody else in the industry was doing." (Fauci Exhibit 79 (11/28/2005 Judith Waterer Dep.), at 48:2 - 48:15; *see also* Fauci Exhibit 78 (11/10/2005 Leslie Paoletti Dep.), at 230:10 - 231:4)

Roxane's Response: Undisputed that Roxane witnesses testified as described. The Government's characterizations of the testimony, however, are selective, incomplete and misleading. The testimony cited by the Government indicates that Roxane was unable to sell its furosemide products not just because its furosemide AWPs were "lower" than its competitors', but that they were "*significantly lower* than [its] competitors' AWPs" and "*so far out of line* with [its] competitors" that pharmacies would not purchase its product, regardless of where the contract price was set. (Fauci Ex. 77, 7/26/07 Paoletti Dep. 78 (emphasis added)) As explained by Ms. Waterer, "[i]f there was an exceptional instance where our pricing was out of line – I think I talked about, I believe it was Furosemide – in an exceptional case where it was brought to our attention, we might take steps to bring ourselves into the average or norm of what everybody else is doing." (Tab 276, 5/9/07 Waterer Dep. 103) Further, Roxane considered discontinuing the product only because it would be forced out of the market if it did not change its AWPs to be comparable with its competitors. As Ms. Waterer testified, Roxane "wanted to bring AWP into line with the competitors. The gist of it is that if we didn't do that [bring AWPs into the average or norm], we were out of the market." (*Id.* at 201) Mr. Russillo testified that he "regarded any decision to raise AWPs as needing to be justified," and that he would generally approve such an AWP change if it was necessary to keep Roxane's AWP in line with its competitors. (Tab 253, 1/8/09 Russillo Dep. 166, 180)

Disputed that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. (Roxane SOF at ¶ 120) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to

Paragraph 74.

77. On or about April 17, 2000, Ms. Waterer told Mr. Sykora that she would "look into" raising Roxane's AWPs for furosemide. Ms. Waterer also noted that "a significant price increase may be a bit 'touchy' right now - especially since it's Furosemide (Mylan problems) and since AWP is what the compendia report with the most accuracy." (Fauci Exhibit 76) According to Ms. Waterer, raising the AWPs for furosemide presented an unusual situation, and required the involvement of "senior leadership" including her immediate supervisor, Mr. Russillo, as well as Mr. Russillo's supervisors. (Fauci Exhibit 79 (11/28/2005 Judith Waterer Dep.), at 48:19 - 51:1; Fauci Exhibit 80; Fauci Exhibit 81, at BOEH02708438)

Roxane's Response: Undisputed that the documents and testimony contain the quoted language. The Government's quotations, however, are selective and incomplete; the documents and deposition testimony in their entirety are the best evidence of their respective content. When Ms. Waterer noted that "a significant price increase might be a bit 'touchy' right now - especially since it's Furosemide (Mylan problems)" she was referring to the press coverage of recent Mylan legal problems unrelated to AWP. (Fauci Ex. 76, 4/18/00 Powers Email to Waterer at PAOLETTI 01846; Tab 275, 11/28/05 Waterer Dep. 46-47) Ms. Waterer explained that Mylan had purchased a supplier of the raw material for a number of products, made huge price increases on the raw material it was then selling to its competitors, forcing its competitors to raise their prices. (*Id.*) Ms. Waterer noted that "[i]t became a huge thing in the press. Mylan was sued." (*Id.* at 47) At the same time, Mylan took huge price increases on furosemide and there was a shortage in the market on the drug's active ingredient. (*Id.*)

Furthermore, the furosemide situation was unusual because Roxane did not monitor the AWP of its competitors, but rather became aware of its AWP disparity from customer complaints. As Ms. Paoletti testified,

> [I]n many cases, I suspect that our AWP was lower than competitors, but it wasn't significantly lower to the point where it impacted our business. And in those cases, we – I mean, we didn't monitor AWPs of our competitors. We – in the furosemide instance, it was brought to our attention that it doesn't matter what contract price you give me, I'm not going to buy your product and this is why.

(Tab 248, 7/26/07 Paoletti Dep. 83-84) Ms. Waterer explained that "[a]t the time we had never done anything like this before. We had never run into, that I recall, an instance of an AWP of this magnitude. There wasn't any formal process in line for changing prices, other than recommending a price and having it signed off on the standard form." (Fauci Ex. 79, 11/28/05 Waterer Dep. 49)

In addition, while Ms. Waterer may have believed that Mr. Russillo's supervisors had to

be involved in approving changes to furosemide pricing, Mr. Russillo testified that he had the authority to approve changes himself, and only consulted with Roxane's President, Werner Gerstenberg, at his discretion. He does not recall consulting Mr. Gerstenberg regarding furosemide. (Tab 253, 1/8/09 Russillo Dep. 98, 167)

Disputed that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. (Roxane SOF at ¶ 120) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: Roxane claims that when Ms. Waterer noted that "a significant price increase might be a bit 'touchy' right now" she was referring to the press coverage of recent Mylan legal problems unrelated to AWP. This fails to raise a disputed issue as to any fact material to the United States' motion for summary judgment. In any event, Roxane's attempt to explain away Ms. Waterer's statement is unconvincing. The evidence plainly supports the inference that Roxane was concerned about raising its AWPs due to government scrutiny of inflated AWPs. First, the "Mylan legal problems" relate to an investigation by the Federal Trade Commission into whether Mylan Laboratories engaged in anti-competitive behavior by "locking up" the active ingredient for certain pharmaceutical products; the investigation did *not* relate to furosemide at all. (*See*, *e.g.*, Fauci Reply Exhibit 186 (11/2/2005 Sykora Dep.), at 83:22 - 84:14; Fauci Reply Exhibit 187) Second, Robert Sykora, Director of National Accounts and the recipient of the email in question, testified that he could not think of "any reason why any alleged illegal monopoly by Mylan . . . would cause there to be sensitivities about raising AWPs." (12/4/2008 Sykora Dep., at 72:14 - 72:18) Further

answering, *see infra* United States' Reply to Roxane's Response to Paragraph 80.

78. On or about April 18, 2000, John Powers (then an employee in Roxane's Contracts Department) sent an email to Ms. Waterer, stating that while he appreciated her "comments regarding the sensitivity of a significant Furosemide increase at this time," Roxane had over 200 accounts for furosemide, and sales were significantly below expected levels. (Fauci Exhibit 76)

Roxane's Response: Undisputed that the document contains the quoted language. The Government's quotations, however, are selective and incomplete; the document in its entirety is the best evidence of its content. Ms. Waterer had previously noted that "a significant price increase might be a bit 'touchy' right now- especially since it's Furosemide (Mylan problems)." (Fauci Ex. 76, 4/18/00 Powers Email to Waterer at PAOLETTI 01846) She was referring to the press coverage of recent Mylan legal problems unrelated to AWP. (Tab 275, 11/28/05 Waterer Dep. 46-47) Ms. Waterer explained that Mylan had purchased a supplier of the raw material for a number of products, made huge price increases on the raw material it was then selling to its competitors, forcing its competitors to raise their prices. (*Id.*) Ms. Waterer noted that "[i]t became a huge thing in the press. Mylan was sued." (*Id.* at 47) At the same time, Mylan took huge price increases on furosemide and there was a shortage in the market on the drug's active ingredient. (*Id.*)

Disputed that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. (Roxane SOF at ¶ 120) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 77.

79. Ms. Waterer subsequently asked Mr. Sykora to prepare a "concise summary of customer comments, requests and documentation regarding Furosemide AWP." (Fauci Exhibit 80) In an email dated June 28, 2000, Ms. Waterer stated that Mr. Russillo (her immediate supervisor) was "aware of the issue and [] willing to champion it - provided we have an extremely solid and well documented background." (*Id.*; *see also* Fauci Exhibit 79 (11/28/2005 Judith Waterer Dep.), at 48:19 - 51:1) Ms. Waterer followed up with Mr. Sykora on July 7, 2000, and

> reiterated that Mr. Russillo was willing to support the AWP increase, "provided we have solid supporting information." (Fauci Exhibit 82)

Roxane's Response: Undisputed that the documents and testimony contain the quoted language. The Government's quotations, however, are selective and incomplete; the documents and deposition testimony in their entirety are the best evidence of their respective content. While Ms. Waterer may have believed that Mr. Russillo needed to "champion" the price change to his supervisors, Mr. Russillo testified that he had the authority to approve changes himself, and only consulted with Roxane's President, Werner Gerstenberg, at his discretion. (Tab 253, 1/8/09 Russillo Dep. 98, 167) He does not recall consulting Mr. Gerstenberg regarding furosemide. (*Id.*) Mr. Russillo explained that being "willing to champion" and "support" the AWP increase meant that he would be willing to approve it provided there was proper documentation. (*Id.* at 163-64, 170) Mr. Russillo testified that he generally wanted to see documentation that would "show [him] reason for changing AWP to be competitive." (*Id.* at 165-66)

Disputed that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. (Roxane SOF at ¶ 120) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 74.

80. Mr. Sykora responded to Ms. Waterer's inquiry as follows:

> I feel that you've thrown Furo onto my lap when the entire generic line AWPs need to be reviewed and adjusted. The most consistent complaint I hear from retail customers is [] our AWPs (which is better than a year ago when it was our service level). ***I realize there is political pressure on AWP currently but itshould not run our business. Logic dictates that no matter what the AWP is, if big brother wants to punish, they will so why not make some money meanwhile***. We could have and should have changed the AWP on furo and other products

> months ago and no amount of documentation is going to mitigate the risk. I can put some documentation together but do not want to take my focus off of customers if we're not really serious about implementing AWP changes. Is this the real deal or busy work?

(*Id*.) (emphasis supplied)

Roxane's Response: Undisputed that the document contains the quoted language, except that Roxane disputes that the document contained a word or words between "is" and "our" where the Government inserted a "[]." The Government's quotations, however, are selective, incomplete, and misleading. Mr. Sykora explained that the "political pressure on AWP" mentioned in his email referred to "pressure from Boehringer Ingelheim," and the "risk" was the Federal Trade Commission's investigation of Mylan regarding its virtual monopoly on certain drugs. (Tab 263, 12/4/08 Sykora Dep. 78-82; Tab 262, 11/2/05 Sykora Dep. 83-84, 94-96, 98-99) Mr. Sykora also explained that "big brother" referred to the Boehringer corporate parent, not the Government. (Tab 263, 12/4/08 Sykora Dep. 82-83, 86; Tab 262, 11/2/05 Sykora Dep. 96-98)

After Roxane sets an AWP for a drug, it generally does not change its AWP. (Roxane SOF at ¶ 106) Ms. Paoletti explained "we didn't monitor AWPs of our competitors. We – in the furosemide instance, it was brought to our attention that it doesn't matter what contract price you give me, I'm not going to buy your product and this is why." (Tab 248, 7/26/07 Paoletti Dep. 83-84) Mr. Sykora was unsure whether the request for documentation regarding an AWP change was "…the real deal or busy work." (Fauci Ex. 82, 7/7/00 Waterer Email to Sykora) Ms. Waterer noted that, "[a]t the time we had never done anything like this before. We had never run into, that I recall, an instance of an AWP of this magnitude. There wasn't any formal process in line for changing prices, other than recommending a price and having it signed off on the standard form." (Tab 275, 11/28/05 Waterer Dep. 49)

Disputed that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. (Roxane SOF at ¶ 120) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: Roxane fails to raise a disputed issue as to any fact

material to the United States' motion for summary judgment. In any event, Roxane's attempt to explain away Mr. Sykora's statement is unconvincing. While Mr. Sykora testified that the phrases "big brother" and "political pressure on AWP" refer to "pressure from Boehringer Ingelheim," others Roxane employees had a different interpretation. Tom Russillo, who was then in charge of Roxane's multi-source marketing, and received the email in question, testified that he understood Mr. Sykora to be "referring to the fact that he is aware that there are lawsuits pending on AWPs and there are perceptions that AWPs have been used incorrectly in the industry." (Fauci Reply Exhibit 189 (1/8/2009 Russillo Dep.), at 171:13 - 171:20) Further answering, *see supra* United States' Reply to Roxane's Response to Paragraph 77.

81. Mr. Russillo responded to Mr. Sykora by email later that day. Mr. Russillo stated, "Bob, I assure it's real. To get the approval we need. . . we need some 'hard' info. Don't shoot the messenger, Judy is only doing what I asked her to do. Rich can assure you of the mood in BI." (Fauci Exhibit 83) Mr. Russillo testified that in order to support an AWP increase, he would have needed to see documentation showing that Roxane was matching the AWP of one of its competitors. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 165:15 - 166:9)

Roxane's Response: Undisputed that the document contains the quoted language, except to the extent that the Government omitted the word "you" in the quote, "Bob, I assure [you] it's real." (Fauci Ex. 83, 7/7/00 Russillo E-mail to Sykora) The Government's quotation, however, is selective and incomplete; the document in its entirety is the best evidence of its content.

Disputed that Mr. Russillo testified that "in order to support an AWP increase, he would have needed to see documentation showing that Roxane was matching the AWP of one of its competitors." This alleged fact is not supported by the Government's proffered evidence. Mr. Russillo testified that he needed to see documentation that would "show [him] reason for changing AWP to be competitive," and that documentation showing that "the AWP change was necessary to make Roxane's AWPs as high as its competitors" would have, "[i]n *general*" been *sufficient* for him to approve the change, not that that particular type of documentation was necessary in this instance. (Fauci Ex. 13, 1/8/09 Russillo Dep. 165-66 (emphasis added)) Nor did Mr. Russillo state that documentation that Roxane was matching the AWP of just *one* of its competitors would have been sufficient. (*Id.*)

Disputed that this alleged fact is material to the Government's motion for summary

judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. (Roxane SOF at ¶ 120) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 74.

82. Mr. Russillo also testified that he was aware of government investigations into inflated AWPs by this time frame, (*id*., at 54:19 - 54:22, 172:13 - 173:17) and that such investigations were a concern to him and to Boehringer Ingelheim in evaluating the proposed furosemide AWP increase. (*Id*., at 166:7 - 166:9, 179:22 - 180:16) Mr. Russillo stated that he would not have endorsed the AWP increase for furosemide unless he believed it was authorized by his superiors. (*Id*., at 172:18 - 174:4, 191:19 - 194:20, 221:22 - 223:1)

Roxane's Response: Undisputed that Mr. Russillo became aware that the government was investigating "inflated AWPs" by the late 1990s. Roxane disputes that its AWPs were "inflated" as Roxane did not believe AWPs to be actual averages of acquisition costs and believed the Government had the same understanding. (Roxane SOF ¶¶ 99-102) Undisputed that Mr. Russillo testified that the government's investigations were a concern to him, but the testimony that Boehringer Ingelheim was "sensitive to AWP changes" referred to AWP changes generally, not to the furosemide AWP increase specifically. (Fauci Ex. 13, 1/8/09 Russillo Dep. 180) Roxane disputes that Mr. Russillo testified that Boehringer Ingelheim "evaluated" decisions regarding AWPs or evaluated the furosemide price increase. This is not supported by the referenced testimony. The testimony cited by the Government is selective and incomplete; the deposition testimony in its entirety is the best evidence of its content.

Roxane disputes that Mr. Russillo testified that he would not have endorsed the AWP increase for furosemide unless he believed it was "authorized" by his superiors. Mr. Russillo stated that he could approve AWP increases, and that he "did not need approval from Boehringer Ingelheim in Connecticut, unless [he] felt there were circumstances that [he] needed to review with Werner Gerstenberg." (Tab 253, 1/8/09 Russillo Dep. 178-79) Mr. Russillo testified,

Q: If you made a marketing decision on a Roxane's product, did you have to run it by Mr. Gerstenberg?

A: Not normally, no.

Q: Were there occasions when you needed to have Mr. Gerstenberg approve a Roxane marketing decision?

A: Those occasions would have been limited. And they would have been at my discretion to advise him, as he was my supervisor.

(*Id.* at 28-29) If Mr. Russillo consulted Mr. Gerstenberg, Mr. Gerstenberg "would have been acting as the president of Roxane." (*Id.* at 174-75)

Further, with respect to the furosemide increase specifically, Mr. Russillo stated: If I thought it was justified, I would have approved it. And I believe that the people you're referring to, BIC or BIPI or whomever, would not have had any objection. I wouldn't have signed off on it if I thought there was going to be a problem.

Q: BY MR. FAUCI: You wouldn't have signed off on it without their approving?

A: I wouldn't have signed off on it if I thought it was going to be a problem. If I was concerned about it, I would have called Werner Gerstenberg and told him what I thought was going on and what I thought should be done. And then he would have either agreed or disagreed.

(*Id.* at 173-74) Mr. Russillo testified that, if an AWP was raised in order to remain competitive, it "was [his] decision to do it," and that he was authorized by his superior to make that type of decision. (*Id.* at 222-23)

Roxane further states that it understood AWP to be a reference point generally tied to the branded version of a multisource drug. At launch Roxane generally set AWP at 10% below the corresponding brand's AWP. Roxane understood this to be the standard industry practice. (Roxane SOF at ¶ 99) Roxane believed that the industry and the Government shared its understanding of AWP. (Roxane SOF at ¶ 102) Ms. Waterer testified "[a]nd again, when you said you're using the term loosely AWP inflation, the industry understands what AWP is. It's a term that has been around for many, many, many years. And people in the industry and people that are familiar with AWP don't believe that AWP is an actual calculated average of some sort of pricing that wholesalers have to some sort of somebody else, and we don't believe that the government thinks that either. And there's a myriad of reasons why it would be irrational to believe that." (Roxane SOF at ¶¶ 99-102; Tab 278, 12/12/08 Waterer Dep. 142) Mr. Russillo also testified that he "regarded any decision to raise AWPs as needing to be justified." (Fauci Ex. 13, 1/8/09 Russillo Dep. 166, 180) Further, Roxane believed that it was in compliance with any relevant laws, as Mr. Russillo testified: "I was not aware of any laws that we would have

been in danger of violating. We've talked about AWP. We were – we believed we were following all the requirements." (Tab 253, 1/8/09 Russillo Dep. 283)

Disputed that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. (Roxane SOF at ¶ 120) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 74.

83. On or about July 26, 2000, Mr. Sykora submitted a "sales justification for an upward adjustment in the AWP of Furosemide." (Fauci Exhibit 84) The sales justification noted that a number of customers had rejected Roxane's bids for furosemide business due to Roxane's low AWP, which caused customers to have "worse profitability" when dispensing Roxane's products. (*Id*., at RLI-AWP-00330563) Mr. Sykora stated by that by raising its AWPs Roxane could "remove the barrier to securing additional Furosemide business from the customer's perspective." (*Id*.) Mr. Sykora also noted that had Roxane secured additional Furosemide accounts in 1999, it could have meant $610,000 to $6.1 million in increased revenue. (*Id*., at RLI-AWP-00330565)

Roxane's Response: Undisputed that the document contains the quoted language. The Government's quotations, however, are selective, incomplete, and misleading; the document in its entirety is the best evidence of its content. Mr. Sykora's reference to raising Roxane's AWPs concerned "raising [its] AWP *to reflect that of the other generic Furosemide*" – in a context where Roxane understood that it not only had the lowest AWP for Furosemide in the generic market, but also that its AWP was "extremely out of line" with the rest of the market's AWPs. (Fauci Ex. 84, 7/26/00 Waterer E-mail to Paoletti at RLI-AWP-00330563 (emphasis added); Tab 275, 11/28/05 Waterer Dep. 48) Roxane became aware of its AWP disparity from customer complaints. As Ms. Paoletti testified, "we didn't monitor AWPs of our competitors. We – in the furosemide instance, it was brought to our attention that it doesn't matter what contract price you give me, I'm not going to buy your product and this is why." (Tab 248, 7/26/07 Paoletti Dep. 83-84) Faced with these complaints, Roxane needed "to bring AWP into line with the competitors. The gist of it is that if we didn't do that, we were out of the market." (Tab 276, 5/9/07 Waterer Dep. 201)

Disputed that customers rejected Roxane's bids for furosemide business due to Roxane's "low" AWP. The document states that Roxane had the "*lowest* AWP *of all the generic Furosemide*," and that as a result, customers rejected Roxane's bids "even though [its] contract prices have been competitive." (Fauci Ex. 84, 7/26/00 Waterer E-mail to Paoletti at RLI-AWP-00330563 (emphasis added))

Disputed that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. (Roxane SOF at ¶ 120) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 74.

84. Roxane ultimately raised the AWPs on its furosemide product by as much as 300% in August 2000. For example, Roxane increased the AWP for its 1000 tablet (20 mg) product from $36.05 to $139.90. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 189:1 – 190:1; Fauci Exhibit 11 (12/4/2008 Robert Sykora Dep.), at 109:1 - 110:13; Fauci Exhibit 85)

Roxane's Response: Undisputed, but the proffered testimony is selective, incomplete, and misleading; the depositions in their entirety are the best evidence of their respective content. Roxane understood AWP to be a reference point generally tied to the branded version of a multisource drug. At launch Roxane generally set AWP at 10% below the corresponding brand's AWP. Roxane understood this to be the standard industry practice. (Roxane SOF at ¶ 99) Roxane believed that the industry and the Government shared its understanding of AWP. (Roxane SOF at ¶¶ 99-102) After Roxane sets an AWP for a drug, it generally does not change its AWP. (Roxane SOF at ¶ 106)

One exception to this practice is when a customer complains and points out that Roxane's AWP is significantly lower than its competitors. (*Id.*) Roxane received customer complaints that its furosemide AWP was out of line with the AWPs for that drug in the rest of the market. (Tab 276, 5/9/07 Waterer Dep. 75-76) Roxane's furosemide AWPs were "significantly lower than [its] competitors' AWPs" and "so far out of line with [its] competitors" that pharmacies would not purchase its product, regardless of where the contract price was set. (Tab 248, 7/26/07 Paoletti Dep. 78) As explained by Ms. Waterer, "[i]f there was an exceptional instance where

our pricing was out of line – I think I talked about, I believe it was Furosemide – in an exceptional case where it was brought to our attention, we might take steps to bring ourselves into the average or norm of what everyone else is doing." (Tab 276, 5/9/07 Waterer Dep. 103) As Ms. Waterer testified, Roxane "wanted to bring AWP into line with the competitors. The gist of it is that if we didn't do that, we were out of the market." (*Id.* at 201) Mr. Russillo testified that he "regarded any decision to raise AWPs as needing to be justified," and that he would generally approve such an AWP change if it was necessary to keep Roxane's AWP in line with its competitors. (Tab 253, 1/8/09 Russillo Dep. 165-66, 180)

Disputed that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. (Roxane SOF at ¶ 120) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.* 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 74.

85. The sales justification memo drafted by Mr. Sykora stated that the contract price for the 1000 tablet (20 mg) product was approximately $10.00, compared with the new AWP of $139.90. (Fauci Exhibit 84, at RLI-AWP-00004514; Fauci Exhibit 3 (Platt Decl.), Graph A5 and Summary A5)

Roxane's Response: Undisputed that the document included the contract price of $10.00 for the 1000 tablet, 20 mg furosemide product and also included an AWP listed as $139.90. However, the document in its entirety is the best evidence of its content.

Roxane further states that it understood AWP to be a reference point generally tied to the branded version of a multisource drug. At launch Roxane generally set AWP at 10% below the corresponding brand's AWP. Roxane understood this to be the standard industry practice. (Roxane SOF at ¶ 99) Roxane believed that the industry and the government shared its understanding of AWP. (Roxane SOF at ¶¶ 99-102) After Roxane sets an AWP for a drug, it generally does not change its AWP. (Roxane SOF at ¶ 106)

One exception to this practice is when a customer complains and points out that Roxane's AWP is significantly lower than its competitors. (*Id.*) Roxane received customer complaints that its furosemide AWP was out of line with the AWPs for that drug in the rest of the market.

(Tab 276, 5/9/07 Waterer Dep. 74-76) Roxane's furosemide AWPs were "significantly lower than [its] competitors' AWPs" and "so far out of line with [its] competitors" that pharmacies would not purchase its product, regardless of where the contract price was set. (Tab 248, 7/26/07 Paoletti Dep. 78) As explained by Ms. Waterer, "[i]f there was an exceptional instance where our pricing was out of line – I think I talked about, I believe it was Furosemide – in an exceptional case where it was brought to our attention, we might take steps to bring ourselves into the average or norm of what everyone else is doing." (Tab 276, 5/9/07 Waterer Dep. 103) As Ms. Waterer testified, Roxane "wanted to bring AWP into line with the competitors. The gist of it is that if we didn't do that, we were out of the market." (*Id.* at 201) Mr. Russillo testified that he "regarded any decision to raise AWPs as needing to be justified," and that he would generally approve such an AWP change if it was necessary to keep Roxane's AWP in line with its competitors. (Tab 253, 1/8/09 Russillo Dep. 165-66, 180)

Disputed that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. (Roxane SOF at ¶ 120) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.* 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts) In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 74.

86. On or about August 2, 2000, Ms. Waterer sent an email to several personnel at Roxane, notifying them that "Tom Russillo just called me, and said he'd gotten the official OK to implement the Furosemide price changes recently circulated for approval." (Fauci Exhibit 85) Ms. Waterer informed Mr. Sykora that she was "really counting on your gang to deliver the $610,000 to $6,100,000 new business you committed to in the Opportunity section of your AWP assessment." (*Id.*)

Roxane's Response: Undisputed that the document contains the quoted language. The Government's quotations, however, are selective and incomplete; the document in its entirety is the best evidence of its content. Roxane further states that while Ms. Waterer may have believed that Mr. Russillo needed approval for the furosemide pricing change, Mr. Russillo testified that he had the authority to approve changes himself, and only consulted with Roxane's President, Werner Gerstenberg, at his discretion. (Tab 253, 1/8/09 Russillo Dep. 98, *see also* Roxane's Resp. to US Roxane SOF at ¶ 82) He does not recall consulting Mr. Gerstenberg regarding furosemide. (Tab 253, 1/8/09 Russillo Dep. 98) Mr. Russillo testified that he "would probably

have told her [he] got the okay, as [he] suggested before, but [he] may not have talked to anybody about it." (*Id.* at 184) Mr. Russillo gave Ms. Waterer the impression that he needed further approval for AWP changes because he "wanted to make sure she realized how important these kind of things were." (*Id.* at 185) Disputed that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. (Roxane SOF at ¶ 120) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 74.

87. During this time frame, Roxane's sales prices to customers for its furosemide products were not increasing. (Fauci Exhibit 3 (Platt Decl.), Graph A5 and Summary of A5; Fauci Exhibit 77 (7/26/2007 Leslie Paoletti Dep.), at 77:13 - 78:2)

Roxane's Response: Undisputed. Roxane, however, objects to the expert declaration the Government references as it is not supported by citations to the record as required by Local Rule 56.1. (Fauci Ex. 3, Declaration of Platt (filed under seal) at Graph A5 and Summary of A5) *See O'Brien*, 440 Supp. 2d at 5 n.1 (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule 56.1). Roxane also disputes that the "contract prices" listed in the Government's expert declaration accurately reflect Roxane's indirect sales prices to its customers for furosemide. (*See* Roxane's Responses to US Roxane SOF at ¶¶ 26, 28, *supra*)

Roxane further states that it understood AWP to be a reference point generally tied to the branded version of a multisource drug. At launch Roxane generally set AWP at 10% below the corresponding brand's AWP. Roxane understood this to be the standard industry practice. (Roxane SOF at ¶ 99) Roxane believed that the industry and the government shared its understanding of AWP. (Roxane SOF at ¶¶ 99-102) After Roxane sets an AWP for a drug, it generally does not change its AWP. (Roxane SOF at ¶ 106)

One exception to this practice is when a customer complains and points out that Roxane's AWP is significantly lower than its competitors. (*Id.*) Roxane received customer complaints that its furosemide AWP was out of line with the AWPs for that drug in the rest of the market.

(Tab 276, 5/9/07 Waterer Dep. 74-76) Roxane's furosemide AWPs were "significantly lower than [its] competitors' AWPs" and "so far out of line with [its] competitors" that pharmacies would not purchase its product, regardless of where the contract price was set. (Fauci Ex. 77, 7/26/07 Paoletti Dep. 78) As explained by Ms. Waterer, "[i]f there was an exceptional instance where our pricing was out of line – I think I talked about, I believe it was Furosemide – in an exceptional case where it was brought to our attention, we might take steps to bring ourselves into the average or norm of what everyone else is doing." (Tab 276, 5/9/07 Waterer Dep. 103) As Ms. Waterer testified, Roxane "wanted to bring AWP into line with the competitors. The gist of it is that if we didn't do that, we were out of the market." (*Id.* at 201) Mr. Russillo testified that he "regarded any decision to raise AWPs as needing to be justified," and that he would generally approve such an AWP change if it was necessary to keep Roxane's AWP in line with its competitors. (Tab 253, 1/8/09 Russillo Dep. 165-66, 180)

Disputed that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. (Roxane SOF at ¶ 120) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.* 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 74.

88. On August 2, Mr. Sykora sent an email announcing new sales of furosemide: "Ask and ye shall receive! Based on the info. below, Hannaford Bros. awarded us Furo all strengths (2,000 bottles of furo 40 mg 1000) and OptiSource has awarded us all strengths as well (unit volume being assembled). Steven is contacting CVS to see if there is still an opportunity to garner that biz. Crank up the machines, we're rocking on the furo train!!!! (Fauci Exhibit 85) Several Roxane employees confirmed that furosemide sales increased following the AWP increase. For example, Mr. Russillo testified that by raising the furosemide AWPs, Roxane increased the reimbursement paid to its customers, which helped Roxane win additional furosemide business. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 183:7 - 183:10, 315:8 - 316:2; Fauci Exhibit 78 (11/10/2004 Leslie Paoletti Dep.), at 207:4 - 208:1; Fauci Exhibit 11 (12/4/2008 Robert Sykora Dep.), at 125:11 - 127:3)

Roxane's Response: Undisputed that the document cited for the first sentence contains

the quoted language. Mr. Sykora explained that "[c]rank up the machines, we're rocking on the furo train" meant that the increased production of furosemide would reduce overhead costs per unit across all products. (Tab 262, 11/2/05 Sykora Dep. 132-33) Undisputed that certain Roxane employees have testified that furosemide sales increased.

Roxane disputes that "Mr. Russillo testified that by raising the furosemide AWPs, Roxane increased the reimbursement paid to its customers, which helped Roxane win additional furosemide business." This alleged fact is not supported by the Government's proffered evidence. According to the cited portions of Mr. Russillo's deposition, Mr. Russillo testified that the raised AWPs "would help Roxane win additional business" for furosemide, (Fauci Ex. 13, 1/8/09 Russillo Dep. 183), and that reimbursers "may have" paid more money in reimbursement as a result of AWP increases. (*Id.* at 315-16) The cited testimony does not support a statement that Roxane increased the reimbursement paid to customers, or that any increased reimbursement payments caused Roxane to obtain additional furosemide business. (*Id.*)

Roxane further states that it understood AWP to be a reference point generally tied to the branded version of a multisource drug. At launch Roxane generally set AWP at 10% below the corresponding brand's AWP. Roxane understood this to be the standard industry practice. (Roxane SOF at ¶ 99) Roxane believed that the industry and the government shared its understanding of AWP. (*Id.* at ¶¶ 99-102) After Roxane sets an AWP for a drug, it generally does not change its AWP. (Roxane SOF at ¶ 106) One exception to this practice is when a customer complains. Roxane received customer complaints that its furosemide AWP was out of line with the AWPs for that drug in the rest of the market. (Tab 276, 5/9/07 Waterer Dep. 75-76) Roxane's furosemide AWPs were "significantly lower than [its] competitors' AWPs" and "so far out of line with [its] competitors" that pharmacies would not purchase its product, regardless of where the contract price was set. (Tab 248, 7/26/07 Paoletti Dep. 78) As Ms. Waterer testified, Roxane "wanted to bring AWP into line with the competitors. The gist of it is that if we didn't do that, we were out of the market." (Tab 276, 5/9/07 Waterer Dep. 201)

Disputed that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. (Roxane SOF at ¶ 120) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide. (US Cons. Memo re Roxane at 13, n.11)

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 74.

C. Roxane's Branded Generic Products

1. Oramorph SR

89. Oramorph SR is a sustained release morphine product which Roxane marketed in the chronic pain/controlled release market. (Fauci Exhibit 86, at RLI-AWP–00170480; Fauci Exhibit 65 (12/8/2008 Colin Carr-Hall Dep.), at 66:13 - 66:18) Oramorph SR was a multi-source product and competed with MS Contin, a branded product marketed by Purdue Frederick. (Fauci Exhibit 86; *see also* Fauci Exhibit 65

(12/8/2008 Colin Carr-Hall Dep.), at 151:15 - 152:14)

Roxane's Response: Undisputed that Oramorph SR is a sustained release morphine product that Roxane marketed in the chronic pain/controlled release market. Also undisputed that Oramorph SR competed with MS Contin, a branded product marketed by Purdue Frederick. Disputed that Oramorph SR was a multi-source product. This alleged fact is not supported by the Government's proffered evidence. Oramorph SR was part of Roxane's brand/branded generic product line. (*See* Roxane Response to US SOF ¶ 7, *supra*) Oramorph SR is not bioequivalent to MS Contin or any other sustained release morphine product. (Tab 285, FDA Orange Book; Tab 286, Oramorph SR-2000 Marketing Plan, 6/26/07 at BOEH00499142-143) Oramorph SR competed with MS Contin and at various times competed with other sustained-release morphine products that were bioequivalent to MS Contin, but no such products were bioequivalent to Oramorph SR. (*Id.*)

90. Although Oramorph SR was a multi-source product, Roxane marketed it as a "branded generic." (Fauci Ex. 31 (11/10/2005 Edward Tupa Dep.), at 110:10–110:14)

Roxane's Response: Disputed. The Government's proffered evidence does not support the alleged fact. The testimony of Mr. Tupa cited by the Government explains that Oramorph SR was part of Roxane's "branded palette of care [sic] products." (Tab 267, 11/10/05 Tupa Dep. 110) Oramorph SR is part of Roxane's brand/branded generic product line, is a single-source product that is BC rated and is not bioequivalent to MS Contin or any other sustained release morphine product. (Roxane Response to US SOF ¶ 7, *supra*; Tab 285, FDA Orange Book; Tab 286, Oramorph SR-2000 Marketing Plan, 6/26/07 at BOEH00499142-143)

91. On or about March 30, 1995, Tom Via (then a National Account Manager) circulated a "Marketing Memo" to sales representatives announcing that Roxane was increasing its prices for Oramorph SR in response to a price increase for MS Contin. (Fauci Exhibit 87) Mr. Via explained that, prior to the price increases, Roxane's AWPs for Oramorph SR had been "40% over WAC," but now the AWPs were "43% more than the WAC." (*Id.*) Mr. Via noted:

> With our old 40% AWP pharmacists were making approximately 7% more when dispensing Oramorph SR instead of MS Contin. As a general rule, a pharmacist will now make around 15% more profit when they switch a prescription from MS Contin to Oramorph SR.

(*Id.*) The March 30, 1995 Marketing Memo also attached a worksheet "illustrating the impact on profit for the retailer with this change." (*Id.*) Mr. Via advised sales representatives that they should "be comfortable enough with the math that you can work the actual numbers out with the pharmacists." (*Id.*)

Roxane's Response: Undisputed that the document contains the quoted language. Roxane disputes that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane as the alleged facts did not occur during the timeframe relevant to the Government's claims. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). The Government's cited document is dated 1995 and the Government's Oramorph SR claims are limited to 1999-2001. (U.S. Cons. Memo. as to Roxane, at 13 n.11) Roxane further disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to Oramorph SR. (*Id.*)
In addition, the Government's quotations from the document are selective, incomplete, and misleading; the document in its entirety is the best evidence of its content. The document cited by the Government refers to third-party reimbursement generally, not government payors specifically, and the "spread" referenced in the document refers to the difference between AWP and WAC, not AWP and acquisition cost or WAC and acquisition cost as the Government implies. The larger "spread" vis-à-vis MS Contin between the AWP and WAC for Oramorph SR resulted from Roxane's lower WAC, not a higher AWP. (Tab 259, 8/5/08 Shaffer Dep. 392-93) Indeed, Roxane's AWP for Oramorph SR was generally less than MS Contin. (*Id.*) Further, the document cited by the Government pertains to a third-party reimbursement methodology based on a percent off of the "spread" between AWP and WAC; this methodology is not used by Medicare or Medicaid programs. As such, this fact is not material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

Moreover, the Government references no testimony that Roxane's sales force ever used the points in Mr. Via's draft, non-final, internal memo when marketing Oramorph SR to customers. On the contrary, the testimony demonstrates that Roxane marketed Oramorph SR

based on its price advantage over competitive products – Oramorph was priced 30-40% less than MS Contin – and the product's efficacy in treating certain therapeutic indications. (Tab 258, 5/21/08 Shaffer Dep. 89-94, 143, 150; Tab 259, 8/5/08 Shaffer Dep. 390-91) Roxane did not market Oramorph SR to pharmacies on the basis of increased Medicare or Medicaid reimbursement. (Tab 269, 10/18/05 Via Dep. 40-41, 51-54; Tab 258, 5/21/08 Shaffer Dep. 94-95; Tab 259, 8/5/08 Shaffer Dep. 388-92) In fact, Roxane marketed Oramorph SR primarily to physicians and hospice providers. (Tab 258, 5/21/08 Shaffer Dep. 54-55; Tab 259, 8/5/08 Shaffer Dep. 385-88) The Roxane sales force therefore had no incentive to market any "spread" because physicians are not reimbursed by state Medicaid programs for dispensing Oramorph SR. (Tab 259, 8/5/08 Shaffer Dep. 385-88) Further, the alleged fact is not relevant to the Government's Medicare claims because Medicare reimbursed providers for generic drugs based on the median generic AWP, and thus, individual manufacturers' AWPs were irrelevant as providers received the same Medicare reimbursement regardless of which manufacturers' product they purchased. Therefore, there was no incentive for manufacturers to "market the spread" based on higher AWP prices. (Tab 254, 5/12/09 Scott Morton Dep. 184-86; Tab 255, 5/13/09 Scott Morton Dep. 321-22, 326; Tab 279, 5/21/09 Williams Dep. 280-81)

UNITED STATES' REPLY: Roxane's attempt to deny the materiality of the evidence against it is futile. The document referenced in Paragraph 91 relates to NDCs which are at issue in this litigation, and explains why Roxane set AWPs for these products the way that it did. In a case about inflated AWPs, evidence of why Roxane set AWPs as it did is of central importance.

92. Mr. Via circulated another Marketing Memo related to Oramorph SR on or about January 31, 1997. (Fauci Exhibit 88) Mr. Via noted that Roxane was increasing the WACs and AWPs for its Oramorph SR products, again in response to price changes for MS Contin. (*Id*.) Mr. Via explained that as "our advantage on spread has increased slightly on all strengths and packages, this will provide an additional incentive for the retailer to stock and dispense Oramorph SR." (*Id*.) Mr. Via again advised sales representatives that "[w]hen presenting Oramorph SR at the pharmacy, first concentrate on this advantage between the spread and then on the cost savings to the patients." (*Id*.)

Roxane's Response: Undisputed that the document contains the quoted language. Roxane also disputes that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane as the alleged facts did not occur during the timeframe relevant to the Government's claims. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). The Government's cited document is dated 1997 and the Government's Oramorph SR

claims are limited to 1999-2001. (US Cons. Memo re Roxane at 13, n.11) Roxane further disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to Oramorph SR. (*Id.*) In addition, the Government's quotations from the document are selective, incomplete, and misleading; the document in its entirety is the best evidence of its content. The document cited by the Government refers to third-party reimbursement generally, not government payors specifically, and the "spread" referenced in the document refers to the difference between AWP and WAC, not AWP and acquisition cost or WAC and acquisition cost as the Government implies. The larger "spread" vis-à-vis MS Contin between the AWP and WAC for Oramorph SR resulted from Roxane's lower WAC, not a higher AWP. (Tab 259, 8/5/08 Shaffer Dep. 392-93) Indeed, Roxane's AWP for Oramorph SR was generally less than MS Contin. (*Id.*) Further, the document cited by the Government pertains to a third-party reimbursement methodology based on a percent off of the "spread" between AWP and WAC; this methodology is not used by Medicare or Medicaid programs. As such, this fact is not material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

Moreover, the Government references no testimony that Roxane's sales force ever used the points in Mr. Via's internal memo when marketing Oramorph SR to customers. On the contrary, the testimony demonstrates that Roxane marketed Oramorph SR based on its price advantage over competitive products – Oramorph was priced 30-40% less than MS Contin – and the product's efficacy in treating certain therapeutic indications. (Tab 258, 5/21/08 Shaffer Dep. 89-94, 143, 150; Tab 259, 8/5/08 Shaffer Dep. 390-91) Roxane did not market Oramorph SR to pharmacies on the basis of increased Medicare or Medicaid reimbursement. (Tab 269, 10/18/05 Via Dep. 40-41, 51-54; Tab 258, 5/21/08 Shaffer Dep. 94-95; Tab 259, 8/5/08 Shaffer Dep. 388-92) Nor did Roxane market Oramorph SR on the basis of "spread." (Tab 258, 5/21/08 Shaffer Dep. 174 ("We did not communicate information on the spread.")) In fact, Roxane marketed Oramorph SR primarily to physicians and hospice providers. (Tab 258, 5/21/08 Shaffer Dep. 54-55; Tab 259, 8/5/08 Shaffer Dep. 385-88) The Roxane sales force therefore had no incentive to market any "spread" because physicians are not reimbursed by state Medicaid programs for dispensing Oramorph SR. (Tab 259, 8/5/08 Shaffer Dep. 385-88)

UNITED STATES' REPLY: *See supra* United States' reply to Roxane's response to Paragraph 92.

93. In January 1998, Roxane again raised the WACs and AWPs on its Oramorph SR products by 5%. (Fauci Exhibit 89) The increased WAC and AWP for the 100 tablet bottle (100 mg) (NDC 00054-4793-25) were $294.67 and $456.74, respectively. (*Id.*) According to a January 12, 1998 Memorandum, the fact that

> Oramorph SR had a greater AWP markup than MS Contin was "based on a strategy" Roxane "implemented several years ago, which was to possess a lower WAC price and offer significant profit advantage for retail pharmacies." (*Id*., at RLI AWP-00166210)

Roxane's Response: Undisputed that the document contains the quoted language. Roxane disputes that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane as the alleged facts did not occur during the timeframe relevant to the Government's claims. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). The Government's cited document is dated 1998 and the Government's Oramorph SR claims are limited to 1999-2001. (US Cons. Memo re Roxane at 13, n.11) Roxane further disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to Oramorph SR. (*Id.*)

In addition, the Government's quotations from the document are selective, incomplete, and misleading; the document in its entirety is the best evidence of its content. The document cited by the Government refers to third-party reimbursement generally, not government payors specifically, and the "spread" referenced in the document refers to the difference between AWP and WAC, not AWP and acquisition cost or WAC and acquisition cost as the Government implies. The larger "spread" vis-à-vis MS Contin between the AWP and WAC for Oramorph SR resulted from Roxane's lower WAC, not a higher AWP. (Tab 259, 8/5/08 Shaffer Dep. 392-93) Indeed, Roxane's AWP for Oramorph SR was generally less than MS Contin. (*Id.*; Fauci Ex. 89, 1/12/98 Smith Letter to Ellexson at 2) Further, the document cited by the Government pertains to a third-party reimbursement methodology based on a percent off of the "spread" between AWP and WAC; this methodology is not used by Medicare or Medicaid programs. As such, this fact is not material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

Moreover, the Government references no testimony that Roxane's sales force ever used the points in Mr. Smith's draft, non-final, internal memo when marketing Oramorph SR to customers. On the contrary, the testimony demonstrates that Roxane marketed Oramorph SR based on its price advantage over competitive products – Oramorph was priced 30-40% less than MS Contin – and the product's efficacy in treating certain therapeutic indications. (Tab 258, 5/21/08 Shaffer Dep. 89-94, 143, 150; Tab 259, 8/5/08 Shaffer Dep. 390-91) Roxane did not market Oramorph SR to pharmacies on the basis of increased Medicare or Medicaid reimbursement. (Tab 269, 10/18/05 Via Dep. 40-41, 51-54; Tab 258, 5/21/08 Shaffer Dep. 94-95; Tab 259, 8/5/08 Shaffer Dep. 388-92) Nor did Roxane market Oramorph SR on the basis of

"spread." (Tab 258, 5/21/08 Shaffer Dep. 174 ("We did not communicate information on the spread.")) In fact, Roxane marketed Oramorph SR primarily to physicians and hospice providers. (Tab 258, 5/21/08 Shaffer Dep. 54-55; Tab 259, 8/5/08 Shaffer Dep. 385-88) The Roxane sales force therefore had no incentive to market any "spread" because physicians are not reimbursed by state Medicaid programs for dispensing Oramorph SR. (Tab 259, 8/5/08 Shaffer Dep. 385-88) Further, the alleged fact is not relevant to the Government's Medicare claims because Medicare reimbursed providers for generic drugs based on the median generic AWP, and thus, individual manufacturers' AWPs were irrelevant as providers received the same Medicare reimbursement regardless of which manufacturers' product they purchased. Therefore, there was no incentive for manufacturers to "market the spread" based on higher AWP prices. (Tab 254, 5/12/09 Scott Morton Dep. 184-86; Tab 255, 5/13/09 Scott Morton Dep. 321-22, 326; Tab 279, 5/21/09 Williams Dep. 280-81)

UNITED STATES' REPLY: *See supra* United States' reply to Roxane's response to Paragraph 91.

94. Roxane raised the AWP and WAC for the 100 tablet bottle (100 mg) again on or about January 1, 1999. (Fauci Exhibit 90) The WAC and AWP for the 100 tablet bottle increased to $309.40 and $479.58, respectively. (*Id*.)

Roxane's Response: Undisputed that the cited document indicates that Roxane increased the AWP for Oramorph SR to $479.58 and the WAC for Oramorph SR to $309.40 on January 11, 1999. However, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to Oramorph SR. (US Cons. Memo re Roxane at 13, n.11) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

95. On or about March 9, 1999, a Roxane employee sent an email announcing that Roxane had "lost" the spread advantage for Oramorph SR. (Fauci Exhibit 91) On March 10, Mr. Powers noted that "[t]his issue needs to be resolved." Mr. Powers stated that among the questions that need to be answered was "the financial/profitability impact if we lower our [Oramorph SR] prices without an AWP change to create a spread advantage over MS Contin[?]" (*Id*.)

Roxane's Response: Undisputed that the cited document includes the quotes in the Government's alleged fact. The Government's quotations, however, are selective, incomplete, and misleading; the document in its entirety is the best evidence of its content. The larger "spread" Roxane had "lost" vis-à-vis MS Contin between the AWP and contract price for

Oramorph SR resulted from Roxane's lower contract price, not a higher AWP. (Tab 259, 8/5/08 Shaffer Dep. 392-93) Indeed, Roxane's AWP for Oramorph SR was generally less than MS Contin. (*Id.*; Fauci Ex. 91, 3/15/99 Comston E-mail to Powers at 2) As such, this fact is not material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

Moreover, the Government references no testimony that Roxane's sales force ever used the "spread" when marketing Oramorph SR to customers. On the contrary, the testimony demonstrates that Roxane marketed Oramorph SR based on its price advantage over competitive products – Oramorph was priced 30-40% less than MS Contin – and the product's efficacy in treating certain therapeutic indications. (Tab 258, 5/21/08 Shaffer Dep. 89-94, 143, 150; Tab 259, 8/5/08 Shaffer Dep. 390-91) Roxane did not market Oramorph SR to pharmacies on the basis of increased Medicare or Medicaid reimbursement. (Tab 269, 10/18/05 Via Dep. 40-41, 51-54; Tab 258, 5/21/08 Shaffer Dep. 94-95; Tab 259, 8/5/08 Shaffer Dep. 388-92) Nor did Roxane market Oramorph SR on the basis of "spread." (Tab 258, 5/21/08 Shaffer Dep. 174 ("We did not communicate information on the spread.")) In fact, Roxane marketed Oramorph SR primarily to physicians and hospice providers. (Tab 258, 5/21/08 Shaffer Dep. 54-55; Tab 259, 8/5/08 Shaffer Dep. 385-88) The Roxane sales force therefore had no incentive to market any "spread" because physicians are not reimbursed by state Medicaid programs or Medicare for dispensing Oramorph SR. (Tab 259, 8/5/08 Shaffer Dep. 385-88) Roxane further disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to Oramorph SR. (US Cons. Memo re Roxane at 13, n.11) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

96. On May 6, 1999, Mr. Powers announced that Roxane had lowered its contract prices for Oramorph SR. Mr. Powers wrote: "In order to compete with the new MS Contin prices appearing on [Long Term Care] and Hospice market contracts, Oramorph SR contract prices will be reduced to cover both price and spread differentials[.]" (Fauci Ex. 92)

Roxane's Response: Undisputed that the cited document includes the quote in the Government's alleged fact. The Government's quotation, however, is selective, incomplete, and misleading; the document in its entirety is the best evidence of its content. The "spread" referenced in the document refers to the difference between MS Contin and Oramorph SR contract prices and the difference between MS Contin and Oramorph SR AWPs, not the difference between AWP and acquisition cost or WAC and acquisition cost as the Government

implies. Moreover, the document cited by the Government makes no mention of third-party reimbursement generally or reimbursement by government payors specifically. As such, this fact is not material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

Roxane marketed Oramorph SR based on its price advantage over competitive products – Oramorph was priced 30-40% less than MS Contin – and the product's efficacy in treating certain therapeutic indications. (Tab 258, 5/21/08 Shaffer Dep. 89-94, 143, 150; Tab 259, 8/5/08 Shaffer Dep. 390-91) In fact, in this instance, Roxane did not increase or otherwise "manipulate" AWP, rather it lowered its contract price to its customers. Roxane did not market Oramorph SR to pharmacies on the basis of increased Medicare or Medicaid reimbursement. (Tab 269, 10/18/05 Via Dep. 40-41, 51-54; Tab 258, 5/21/08 Shaffer Dep. 94-95; Tab 259, 8/5/08 Shaffer Dep. 388-92) Nor did Roxane market Oramorph SR on the basis of "spread." (Tab 258, 5/21/08 Shaffer Dep. 174 ("We did not communicate information on the spread.")) In fact, Roxane marketed Oramorph SR primarily to physicians and hospice providers. (Tab 258, 5/21/08 Shaffer Dep. 54-55) Indeed, the document cited by the Government pertains to long term care and hospice sales, not retail pharmacy sales. The Roxane sales force therefore had no incentive to market any "spread" because physicians are not reimbursed by state Medicaid programs or Medicare for dispensing Oramorph SR. (Tab 259, 8/5/08 Shaffer Dep. 385-88) Roxane further disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to Oramorph SR. (US Cons. Memo re Roxane at 13, n.11) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

97. In early 2000, Roxane again increased the WACs and AWPs for its Oramorph SR products. The WAC and AWP for the 100 tablet bottle (100 mg) were increased to $316.68 and $493.95, respectively. (Fauci Exhibit 93; Fauci Exhibit 3 (Platt Decl.), Graph A4 and Summary A4) A Field Communication announcing the new prices to Roxane's palliative care sales force included a pricing grid comparing prices for Oramorph SR and MS Contin. (Fauci Exhibit 93) The Field Communication instructed the sales force to "[u]tilize this pricing grid as a reference in your pharmacies to demonstrate the lower acquisition cost and higher spread for many of our products." (*Id*.)

Roxane's Response: Undisputed that the cited document indicates Roxane increased the AWP and WAC prices for Oramorph SR in January, 2000 and undisputed that the cited document includes the quote in the Government's alleged fact. The Government's quotations,

however, are selective, incomplete, and misleading; the document in its entirety is the best evidence of its content. The "spread" referenced in the document refers to the difference between AWP and WAC, not AWP and acquisition cost or WAC and acquisition cost as the Government implies. The larger "spread" vis-à-vis the competition between the AWP and WAC for Oramorph SR resulted from Roxane's lower WAC, not a higher AWP. (Tab 259, 8/5/08 Shaffer Dep. 392-93) Indeed, Roxane's AWP for Oramorph SR was generally less than the competition. (Fauci Ex. 93, Palliative Care Field Communication 00-04 at 2; Tab 259, 8/5/08 Shaffer Dep. 392-93) As such, this fact is not material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

Moreover, the Government references no testimony that Roxane's sales force ever used the information in this internal memo when marketing Oramorph SR to customers. Indeed, the memo explains in bold, italicized lettering that "This pricing grid is for representative use only and is not to be copied or distributed in the field." (Fauci Ex. 93 at 1) Contrary to the Government's alleged fact, the testimony demonstrates that Roxane marketed Oramorph SR based on its price advantage over competitive products – Oramorph was priced 30-40% less than MS Contin – and the product's efficacy in treating certain therapeutic indications. (Tab 258, 5/21/08 Shaffer Dep. 89-94, 143, 150; Tab 259, 8/5/08 Shaffer Dep. 390-91) Roxane did not market Oramorph SR to pharmacies on the basis of increased Medicare or Medicaid reimbursement. (Tab 269, 10/18/05 Via Dep. 40-41, 51-54; Tab 258, 5/21/08 Shaffer Dep. 94-95; Tab 259, 8/5/08 Shaffer Dep. 388-92) Nor did Roxane market Oramorph SR on the basis of "spread." (Tab 258, 5/21/08 Shaffer Dep. 174 ("We did not communicate information on the spread.")) In fact, Roxane marketed Oramorph SR primarily to physicians and hospice providers. (Tab 258, 5/21/08 Shaffer Dep. 54-55) The Roxane sales force therefore had no incentive to market any "spread" because physicians are not reimbursed by state Medicaid programs or Medicare for dispensing Oramorph SR. (Tab 259, 8/5/08 Shaffer Dep. 385-88) Roxane further disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to Oramorph SR. (US Cons. Memo re Roxane at 13, n.11) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

2. Roxicodone

98. Roxane marketed "Roxicodone" as a "branded generic" product to treat chronic pain. (Fauci Exhibit 94; Fauci Exhibit 28 (10/31/2008 Sheldon Berkle Dep.), at 234:2 - 234:12) In or around September 2000, Roxane launched the "first and only" 15 and 30 mg Roxicodone tablets (NDCs 00054-4568-25 and 00054-4665-

25). (Fauci Exhibit 94; Fauci Exhibit 95) Prior to September 2000, Roxane only marketed 5 mg Roxicodone tablets. (Fauci Exhibit 1, (5/21/2008 Shaffer Dep.), at 224:11 - 224:14)

Roxane's Response: Undisputed that Roxane marketed several strengths of Roxicodone at various points in time as part of its brand/branded generic palliative care line of products used to treat pain. (*See* Roxane's Resp. to US Roxane SOF at ¶ 7) Only the 15 mg and 30 mg strengths launched in late2000, however, are at issue in this case (US Roxane SOF at ¶ 8, *supra*) Disputed that Roxane "launched" the 15 mg and 30 mg Roxicodone tablets in September 2000 as the Government's proffered evidence does not support this alleged fact. Undisputed, however, that in September 2000, Roxane *was preparing to* launch the "first and only" 15 mg and 30 mg Roxicodone Tablets and that the products were expected to be available for commercial distribution after October 2, 2000. (*See* Fauci Ex. 94, Roxicodone 15/30 mg Launch Plan and Pricing Proposal at Shaffer 001455; Fauci Ex. 95, New Product Introduction re Roxicodone at RLI-TX 19839) Undisputed that prior to September 2000, Roxane only marketed a 5 mg Roxicodone tablet, which is not at issue in this case. Undisputed that Roxane's 15 mg and 30 mg Roxicodone tablets were the "first and only" available at those strengths. Roxane notes, however, that three or six 5 mg tablets could be substituted to reach the same strength and that there were several brand and generic competitors in the 5 mg oxycodone market. (Tab 263, 12/4/08 Sykora Dep. 177; Fauci 94, Roxicodone 15/30 mg Launch Plan and Pricing Proposal at Shaffer 001516) Roxane further states that the 15 mg and 30 mg Roxicodone products at issue in this case were only actively marketed by Roxane for the short time period between late September 2000 and December 2000, when the Roxane palliative care sales force was disbanded, and that in September 2001, Roxane divested the products to Elan Pharma International Ltd. (Tab 259, 8/5/08 Shaffer Dep. 367; Roxane SOF at ¶ 253)

In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to Roxicodone. (US Cons. Memo re Roxane at 13, n. 11) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

99. On or about August 12, 2000, Fred Duy (then a director of "Business Development") sent the "Roxicodone 15/30 mg Launch Plan" to Sheldon Berkle (then Vice President of Marketing at BIPI) and others. At that time, Mr. Duy also transmitted an "initial pricing proposal for Roxicodone 15 and 30 mg Tablets." (Fauci Exhibit 94) The pricing proposal listed as "objectives" to set "reasonable price[s] relative to existing 5 mg tablets" and to ensure there was "no reimbursement incentive for substitution of 5 mg tablets." (*Id*., at Shaffer 001516)

Roxane's Response: Undisputed that on or about August 12, 2000, Fred Duy sent the

Launch Plan and an initial pricing proposal for Roxicodone 15 mg and 30 mg to Mr. Berkle and others. Roxane disputes the titles the Government lists for Mr. Duy and Mr. Berkle as they are not supported by citations to the record as required by Local Rule 56.1. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006) (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule 56.1). Undisputed that the pricing proposal contains the quoted language. The Government's quotations, however, are selective, incomplete and misleading; the document in its entirety is the best evidence of its content. The entirety of the document and witness testimony establish that the prices for Roxicodone 15 mg and 30 mg were set "reasonably comparable" to competitive prices for 5 mg tablets and at a level such that retailer profit would be "similar" to 5 mg generic oxycodone products, with the goal that there would be no incentive for the pharmacist to substitute three or six 5 mg generic tablets for prescriptions of Roxicodone 15 mg or 30 mg. In other words, Roxane set the prices so the new strengths would not be disadvantaged at the pharmacy level and would remain competitive. (Fauci Ex. 94, Roxicodone 15/30 mg Launch Plan and Pricing Proposal at Shaffer 001516; Tab 258, 5/21/08 Shaffer Dep. 218-19) In addition, Roxane states that its core sales message for Roxicodone was directed to physicians, not pharmacies, and focused on the therapeutic advantages of the unique 15 mg and 30 mg strengths. (Fauci Ex. 94, Roxicodone 15/30 mg Launch Plan and Pricing Proposal at Shaffer 001492-1507; Tab 259, 8/5/08 Shaffer Dep. 369-72; Tab 287, Shaffer Exhibit 27, Roxicodone 15/30 mg Launch Plan Overview Presentation at 8-17) Roxane further states that the 15 mg and 30 mg Roxicodone products were only actively marketed by Roxane for the short time period between late September 2000 and December 2000, when the Roxane palliative care sales force was disbanded, and that in September 2001 the products were divested to Elan Pharma International Ltd. (Tab 259, 8/5/08 Shaffer Dep. 367; Roxane SOF at ¶ 253)

In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to Roxicodone. (US Cons. Memo re Roxane at 13, n. 11) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

100. The proposed WAC and AWP for the 100 tablet bottle (15 mg) were $55.00 and $110.00, respectively. (*Id.*) According to the pricing proposal, "[t]he competitive spreads between WACs and AWPs in the class are significantly higher than the normal brand's 16 2/3% to 25%." (*Id.*) The pricing proposal stated that the proposed AWP prices for the 15 and 30 mg Roxicodone products "will provide a similar spread for the pharmacy, so there is no incentive to substitute 5 mg tablets for 15 or 30 mg." (*Id.*; *see also* Fauci Exhibit 10, at RLI-AWP–00161992)

Roxane's Response: Undisputed that the proposed WAC and AWP for the 100 tablet bottle (15 mg) Roxicodone launched in later 2000 were as stated and that the document

referenced contains the quoted language. The Government's quotations, however, are selective, incomplete and misleading. The Government's first quote is not addressing Roxane's Roxicodone pricing specifically as the Government's paragraph implies, but rather follows after a sentence explaining that reimbursement to pharmacies is "normally different for generics versus exclusive products" and therefore is conveying that the competitive spreads between WAC and AWPs for generics are higher than the standard 16 2/3% to 25% for brand products. (Fauci Ex. 94, Roxicodone 15/30 mg Launch Plan and Pricing Proposal at Shaffer 001516) In addition, the entirety of the document and witness testimony establish that the prices for Roxicodone 15 mg and 30 mg were set "reasonably comparable" to competitive prices for 5 mg tablets and at a level such that retailer profit would be "similar" or comparable to 5 mg generic oxycodone products, with the goal that there would be no incentive for the pharmacist to substitute three or six 5 mg generic tablets for prescriptions of Roxicodone 15 mg or 30 mg. In other words, Roxane set the prices so the new strengths would not be disadvantaged at the pharmacy level and would remain competitive. (*Id.*; Tab 258, 5/21/08 Shaffer Dep. 218-19)

Roxane further states that its core sales message for Roxicodone was directed to physicians, not pharmacies, and focused on the therapeutic advantages of the unique 15 mg and 30 mg strengths. (Fauci Ex. 94, Roxicodone 15/30 mg Launch Plan and Pricing Proposal at Shaffer 001492-507; Tab 259, 8/5/08 Shaffer Dep. 369-72; Tab 287, Shaffer Ex. 27, Roxicodone 15/30 mg Tablets Launch Plan Overview Presentation at 8-17) Roxane further states that the 15 mg and 30 mg Roxicodone products were only actively marketed by Roxane for the short time period between late September 2000 and December 2000, when the Roxane palliative care sales force was disbanded, and that in September 2001, the products were divested to Elan Pharma International Ltd. (Tab 259, 8/5/08 Shaffer Dep. 367; Roxane SOF at ¶ 253)
In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to Roxicodone. (US Cons. Memo re Roxane at 13, n. 11) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

101. On or about August 22, 2000, WACs and AWPs for the Roxicodone 15 and 30 mg tablets were submitted for approval. The approval form stated that the proposed prices were "compatible with the reimbursement model that drives retailer profit." (Fauci Exhibit 97) Shortly thereafter, the proposed pricing was approved. (Fauci Exhibit 98)

Roxane's Response: Undisputed that proposed WACs and AWPs for Roxicodone 15 mg and 30 mg tablets were submitted for approval on or about August 22, 2000 and that the approval form contains the quoted language. The Government's quotations, however, are selective, incomplete and misleading. First, the document only references WAC, not AWP, in stating that the prices "are compatible with the reimbursement model that drives retailer profit."

(Fauci Ex. 97, 8/22/00 Roxicodone Pricing Recommendation at BOEH00242612-13) The document also states that the WAC prices are "below but in line with existing Roxicodone 5 mg WAC prices" and "reasonably comparable to competitive prices." (*Id.* at BOEH00242612) Further the entirety of the document and witness testimony establish that "compatible with the reimbursement model that drives retailer profit" means that they were set at a level such that retailer profit would be "similar" to 5 mg oxycodone products and pharmacists would not have an incentive to substitute 3 or 5 mg generic tablets for prescriptions of Roxicodone 15 mg or 30 mg. In other words, Roxane set the prices so the new strengths would not be disadvantaged at the pharmacy level and would remain competitive. (Fauci Ex. 94, Roxicodone 15/30 mg Launch Plan and Pricing Proposal at Shaffer 001516; Fauci Ex. 97, 8/22/00 Roxicodone Pricing Recommendation at BOEH00242613; Tab 258, 5/21/08 Shaffer Dep. 218-19)

In addition, Roxane states that its core and primary sales message for Roxicodone was directed to physicians, not pharmacies, and focused on the therapeutic advantages of the unique 15 mg and 30 mg strengths. (Fauci Ex. 94, Roxicodone 15/30 mg Launch Plan and Pricing Proposal at Shaffer 001492-1507; Tab 259, 8/5/08 Shaffer Dep. 369-72; Tab 287, Shaffer Ex. 27, Roxicodone 15/30 mg Tablets Launch Plan Overview Presentation at 8-17) Roxane further states that the 15 mg and 30 mg Roxicodone products were only actively marketed by Roxane for the short time period between late September 2000 and December 2000, when the Roxane palliative care sales force was disbanded, and that in September 2001, the products were divested to Elan Pharma International Ltd. (Tab 259, 8/5/08 Shaffer Dep. 367; Roxane SOF at ¶ 253) In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to Roxicodone. (US Cons. Memo re Roxane at 13, n. 11) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

102. Around this time frame, Mr. Sykora prepared a series of slides to present to Roxane's palliative care sales force in anticipation of the launch of Roxane's 15/30 mg Roxicodone tablets. (Fauci Exhibit 11 (12/4/2008 Robert Sykora Dep.), at 133:7 - 135:13) One slide noted that Roxicodone 15 mg and 30 mg was typically more profitable for pharmacies to dispense. (Fauci Exhibit 99, at BOEHO1301726) A "Roxicodone 15 mg, 30 mg profit calculator" also was created, showing the increased spread for Roxane's products. (Fauci Exhibit 100)

Roxane's Response: Roxane does not dispute the first sentence of Paragraph 102 or that one slide of Mr. Sykora's presentation stated what the Government describes in the second sentence. However, as Mr. Sykora explained, the purpose of his presentation was to "educate the sales force" that if they worked to get physicians to write prescriptions for 15 mg and 30 mg Roxicodone, the pharmacy would not have an incentive to substitute three or six generic 5 mg tablets for the 15 mg or 30 mg prescription; the sales force had previously complained that the

Roxicodone 5 mg prescriptions they generated at physicians' offices were being substituted at the pharmacies with another generic competitor. (Tab 263, 12/4/08 Sykora Dep. 173-77; Tab 224, 7/25/07 Ciarelli Dep. 68-71) The presentation regarding reimbursement was thus designed to "allay [the sales forces'] fear" of substitution, not to have the sales force "educate the pharmacies on it." (Tab 263, 12/4/08 Sykora Dep. 174-75) Indeed, Mr. Sykora testified that the sales force did not have "enough knowledge or expertise in reimbursement to present something as complicated as what I'm seeing here to a pharmacy and talk about reimbursement." (*Id.*) This is consistent with Mr. Shaffer's testimony that Roxane's core and primary sales message for Roxicodone was directed to physicians, not pharmacies, and focused on the therapeutic advantages of the unique 15 mg and 30 mg strengths. (Fauci Ex. 94, Roxicodone 15/30 mg Launch Plan and Pricing Proposal, at Shaffer 001492-1507; Tab 259, 8/5/08 Shaffer Dep. 369-72; Tab 287, Shaffer Ex. 27, Roxicodone 15/30 mg Tablets Launch Plan Overview Presentation at 8-17)

Moreover, while the referenced slide states that it would "typically" be more profitable to dispense Roxane's product, the more detailed pricing proposals specifically state that Roxane's Roxicodone was priced to be below but "in line with existing Roxicodone 5 mg WAC prices," "reasonably comparable to competitive prices" and to provide a "similar" profit to 5 mg competitors. (Fauci Ex. 94, Roxicodone 15/30 mg Launch Plan and Pricing Proposal at Shaffer 001516; Fauci Ex. 97, 8/22/00 Roxicodone Pricing Recommendation at BOEH00242612-13) Indeed, the documents show that a wide range of AWPs and WACs existed for 5 mg competitors and that Roxane's 15 mg and 30 mg proposed AWPs and WACs fell close to the middle of that range. (*Id.*)

Roxane does not dispute that Fauci 100 is titled "profit calculator" and relates to Roxicodone 15 mg and 30 mg. Roxane disputes that the document shows "the increased spread for Roxane's product" as it is not clear what "increased spread" means and because it is not supported by the proffered evidence. Roxane disputes any implication that this internal, draft document was ever used by Roxane with any pharmacy customer; the Government has cited no testimony or evidence that supports this implication. Nor is there any testimony stating who created the document or for what purpose it was created. Further answering, Roxane states that the 15 mg and 30 mg Roxicodone products were only actively marketed by Roxane for the short time period between late September 2000 and December 2000, when the Roxane palliative care sales force was disbanded, and that in September 2001, the products were divested to Elan Pharma International Ltd. (Tab 259, 8/5/08 Shaffer Dep. 367; Roxane SOF at ¶ 253)

In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to Roxicodone. (US Cons. Memo re Roxane at 13, n. 11) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

103. On or about September 8, 2000, Mark Shaffer (then head of Roxane's Palliative Care Sales Force) circulated a document entitled "Reimbursement Background." (Fauci Exhibit 101) The cover letter transmitting this document stated that "[k]nowledge of pharmaceutical reimbursement practices, especially how they may affect pharmacist acceptance for Roxicodone 15 mg and 30 mg tablets, will play an important part in your successful stocking of those new strengths in your retail accounts after the launch meeting." (*Id.*)

Roxane's Response: Undisputed that Mr. Shaffer circulated the referenced document on or around September 8, 2000 and that the cover letter contains the quoted statement. The Government's quotation, however, is selective, incomplete and misleading; the entirety of the document is the best evidence of its content. Mr. Shaffer explained that this document was provided to the sales force as "an overview, a backgrounder, for-your-information-type document." (Tab 258, 5/21/08 Shaffer Dep. at 244-45) Consistent with Mr. Sykora's testimony, Mr. Shaffer further explained that the sales force was provided background information regarding reimbursement so that the sales force understood generic substitution at the pharmacy would not undermine their work in generating physician prescriptions:

> I think for this particular product launch, as I had mentioned early, it was very important that our people understood that the product was going to be priced so it would not be an issue to drive prescriptions with the physicians because of the generics; and it's important that they had a background and they understood that the company was pricing the product where their job was to go out and educate and detail physicians and prescribers and healthcare professionals on the benefits of Roxicodone 15 and 30 milligrams."

(Tab 258, 5/21/08 Shaffer Dep. 261; Tab 263, 12/4/08 Sykora Dep. 173-78 (he conducted a workshop at the Roxicodone sales launch meeting regarding reimbursement issues to "educate the sales force" and to "allay their fear" of pharmacies substituting generic 5 mg tablets for 15 or 30 mg prescriptions the sales force generated from physicians, not to have the sales force "educate the pharmacies on it"); Tab 224, 7/25/07 Ciarelli Dep. 68-71)) Roxane further notes that the fact that it had to circulate a background information document related to basic reimbursement history, terms and procedures demonstrates how unfamiliar Roxane was with reimbursement in its normal marketing and sales activities.

Further answering, Roxane states that the 15 mg and 30 mg Roxicodone products were only actively marketed by Roxane for the short time period between late September 2000 and December 2000, when the Roxane palliative care sales force was disbanded, and that in September 2001, the products were divested to Elan Pharma International Ltd. (Tab 259, 8/5/08 Shaffer Dep. 367; Roxane SOF at ¶ 253)

In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with

respect to Roxicodone. (US Cons. Memo re Roxane at 13, n. 11) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

104. The Reimbursement Background memorandum included a section entitled "Pharmaceutical Product Reimbursement" which noted that "[a] reimbursement strategy that assists the pharmacist in earning an equitable profit should ultimately pay dividends for the pharmaceutical manufacturer." (*Id*., at Paoletti 20751) The memorandum also discussed the historical background of pharmacy reimbursement, and explained the role of WAC and AWP as follows:

> The WAC (Wholesaler Acquisition Cost) was the list price that pharmaceutical manufacturers charged wholesalers and often less than the list price to non–wholesale direct accounts. Wholesalers marked up their acquisition cost by 20% –25% for resale to their pharmacy customers. These resale prices were referred to as Average Wholesale Prices (AWP) and were meant to reflect an average of suggested list prices that wholesalers charged various customer outlets (e.g., retail pharmacies and physician offices).

(*Id*., at Paoletti 20751 - 52) The memorandum also described AWPs as "commonly used by retailers and others who dispense medications as the basis for many pricing decisions" and as "a surrogate for actual prices when studying prescription price trends." (*Id*., at Paoletti 20756)

Roxane's Response: Undisputed that the document cited includes the referenced quotations, except that the word "was" is missing between "and" and "often" in the second line. The Government's quotations, however, are selective, incomplete and misleading; the entirety of the document is the best evidence of its content. Roxane disputes the implication that Roxane knew, understood or agreed with all of the information contained in the Reimbursement Background memorandum as there is no testimony or evidence that a Roxane employee authored the document and Mr. Shaffer testified that an outside consulting agency may have drafted it. (Tab 258, 5/21/08 Shaffer Dep. 242-43) In addition, Mr. Shaffer is the only witness who testified to reviewing the document, and he repeatedly testified that he did not write it, did not have an understanding at the time of what certain statements in the document meant, was not familiar with the information in the document at the time (including some of the quotes referenced by the Government here) and did not necessarily agree with certain statements in the document. (*Id.* at 247-48, 252-53, 258-59, 263)

Moreover, the Government takes its quotes out of context. The quote describing WAC and AWP was discussing their meanings historically, and goes on to recognize that wholesaler mark-ups were no longer 20-25%, but that nonetheless AWP continued to reflect such a markup. (Fauci Ex. 101, 9/8/00 Reimbursement Background at Paoletti 20752) In addition, the Government leaves out the first sentence of the document's definition of AWP in its last quote, which acknowledges that AWP "is neither an average price nor a price charged by wholesalers, this figure is a vestige of earlier times." (*Id.* at Paoletti 20756) Further, Roxane witnesses testified that they understood and believed others in the industry understood AWP to be a reference point generally tied to the branded version of a multisource drug and that AWP was not intended to and did not represent an actual average of wholesale prices to customers. (Roxane SOF at ¶¶ 99-101)

In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to Roxicodone. (US Cons. Memo re Roxane at 13, n. 11) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

D. Roxane Promoted Reimbursement Spreads As an Inducement to Buy Its Products

105. As noted *supra*, Roxane's promotional literature frequently identified products' AWPs and invited customers to compare AWPs to acquisition costs. (*See supra* Paragraphs 53 and 65; *see also* Fauci Exhibit 43; Fauci Exhibit 61; Fauci Exhibit 22 (9/20/2005 Leslie Paoletti Dep.), at 85:22 - 87:19)

Roxane's Response: Roxane disputes that its promotional literature invited customers to compare AWPs to acquisition costs, let alone frequently did so. This alleged fact is not supported by the Government's proffered evidence. Rather, the Government's evidence shows that when Roxane launched the first generic product (such as with ipratropium bromide and azathioprine) Roxane suggested that customers compare the new generic AWPs and acquisition costs to the brands' AWPs and acquisitions costs as the generics were lower and would provide "cost savings" to the customer. (Fauci Ex. 43, 4/22/96 New Product Announcement re Ipratropium Inhalation Solution UVD (RLI-AWP 00430-904; Fauci Ex. 61, 2/16/96 New Product Announcement for Azathioprine (RLI-AWP 0077298)) Moreover, the testimony the Government cites does not support this alleged fact, as Ms. Paoletti testified only that customers are notified when AWPs and WACs change. (Fauci Ex. 22, 9/20/05 Leslie Paoletti Dep. at 85-87) Roxane incorporates its responses to Paragraphs 53 and 65.

In addition, Roxane disputes that the alleged facts in Paragraph 105 are material to the Government's Medicare claims against Roxane. Because Medicare reimbursed providers for

generic drugs based on the median generic AWP, individual manufacturer's AWPs were irrelevant and providers received the same Medicare reimbursement regardless of which manufacturer's product they purchased. (Tab 254, 5/12/09 Scott Morton Dep. 185-86; Tab 255, 5/13/09 Scott Morton Dep. 321-22, 326; Tab 279, 5/21/09 Williams Dep. 280-81)

106. Roxane commonly provided contract prices and AWPs in its communications with customers. (*See*, *e.g.*, Fauci Exhibit 65 (12/12/2008 Colin Carr-Hall Dep.), at 121:2 – 122:1) Letters sent by Roxane notifying customers of price reductions frequently compared the offered contract price to the AWP. (*See supra* ¶¶ 53, 56, 63, 69, 73) For example, in or around, September 1999, Roxane reduced the price offered to one customer for ipratropium bromide to $14.40, not inclusive of market-share rebates. (Fauci Exhibit 50, at Kutner Deposition Exhibit 7) The letter listed the $14.40 price next to the AWP, which was still $44.06. (*Id.*; *see also* Fauci Exhibit 50, at Kutner Deposition Exhibit 8; Fauci Exhibit 51; Fauci Exhibit 102)

Roxane's Response: Undisputed that Roxane's communications with its customers at times included contract prices and AWPs, but disputed that this occurred frequently as the Government's proffered evidence does not support this fact. Roxane disputes that letters sent by Roxane notifying customers of price reductions "compared" the contract price with the AWP when it merely lists both without comment. Roxane hereby incorporates by reference its responses to Paragraphs 53, 56, 63, 69, and 73. Undisputed that a September 1999 letter listed the contract price for one ipratropium bromide product as $14.40, not inclusive of market-share rebates, and the AWP as $44.06. However, the document in its entirety is the best evidence of its content.

Roxane disputes that the alleged facts in Paragraph 106 are material to the Government's Medicare claims against Roxane. Because Medicare reimbursed providers for generic drugs based on the median generic AWP, individual manufacturer's AWPs were irrelevant and providers received the same Medicare reimbursement regardless of which manufacturer's product they purchased. (Tab 254, 5/12/09 Scott Morton Dep. 185-86; Tab 255, 5/13/09 Scott Morton Dep. 321-22, 326; Tab 279, 5/21/09 Williams Dep. 280-81)

107. When a customer asked that Roxane also include WACs in such letters, Roxane accommodated the request. For example, on or about April 13, 2000, a representative of ANDA Generics, a company with a business address in Florida, requested that "on all future offers, or price revisions [Roxane] list WAC, Contract Price, AWP." (Fauci Exhibit 103) Roxane agreed to do so, and future letters to ANDA Generics listed the WAC in addition to the contract price and AWP. (*See*, *e.g.*, Fauci Exhibit 104; Fauci Exhibit 105; Fauci Exhibit 106)

Roxane's Response: Roxane disputes the first sentence to the extent that it implies that when any customer asked that Roxane include WAC in its letters, Roxane accommodated the

request. This alleged fact is not supported by the Government's proffered evidence, which only indicates that Roxane accommodated the request of one customer, ANDA Generics. Undisputed that the document contains the quoted language. The Government's quotation, however, is selective and incomplete; the document in its entirety is the best evidence of its content. To the extent that the alleged facts are based on Fauci Exhibit 104, Roxane disputes that they are material to the Government's motion for summary judgment or its claims against Roxane because Fauci Exhibit 104 specifically concerns a drug that is not one of the Subject Drugs at issue in this case. (Fauci Ex. 104, 1/4/01 Storck Letter to Movens) In addition, Roxane disputes that this fact is material to the Government's Medicare claims against Roxane as Medicare did not reimburse for prescription drugs on the basis of WAC. Disputed that the alleged facts are material to the Government's Medicare claims against Roxane to the extent that they concern WAC, because Medicare reimbursed providers for generic drugs based on the median generic AWP, not WAC.

108. Roxane employees also promoted reimbursement spreads as a reason to buy Roxane's products. (*See e.g.*, Fauci Exhibit 107 (July 20, 2000 email from John Powers describing conversation with customer and stating "I discussed the AWP spread"); Fauci Exhibit 65 (12/12/2005 Colin Carr-Hall Dep.), at 128:5 - 128:22, 133:21 - 134: 13; *see supra* ¶¶ 91 and 92; Fauci Exhibit 87; Fauci Exhibit 88)

Roxane's Response: Disputed. The Government's proferred evidence does not support the Government's alleged fact that "Roxane employees also promoted reimbursement spreads as a reason to buy Roxane's products." First, Roxane disputes that the proffered evidence is material to the Government's motion for summary judgment or its claims against Roxane because the cited documents concern drugs and/or time periods that are not relevant to this case. (Fauci Ex. 107, 7/20/00 Waterer E-mail to Powers (concerning cyclophosphamide, a drug not at issue in this case, and indicating that the primary issue in obtaining Kaiser's business was whether Roxane would provide a "fixed price agreement"); Tab 222, 12/12/08 Carr-Hall Dep. 126-27 (indicating that the testimony cited in Fauci Exhibit 65 concerned Roxicet, a drug not at issue in this case); U.S. Cons. Memo re Roxane at 13 n.11 (the Government's Oramorph SR claims are limited to 1999-2001); Fauci Ex. 87, 3/30/95 Marketing Memo #2 (concerning Oramorph SR in 1995); Fauci Ex. 88, 1/31/97 Marketing Memo #1 (concerning Oramorph SR in 1997)) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

Undisputed that Fauci Exhibit 107 contains the quoted language. The Government's quotations, however, are selective, incomplete, and misleading; the documents in their entirety are the best evidence of its content. While Mr. Powers mentions that he discussed the "AWP spread" with one customer, at one point in time, with regard to CCP (a drug not at issue), the document does not indicate to what Mr. Powers was referring or what Mr. Powers actually said. (Fauci Ex. 107, 7/20/00 Waterer E-mail to Powers) In addition, Mr. Powers stated that he also

discussed "the additional price reduction, the market share program, [and] the sole generic positioning" and that the customer was looking for a "fixed price" agreement better than the one offered by Roxane's competitor. (*Id.*) Further, Ms. Waterer's response indicates that Roxane would attempt to "do something" to "meet the competitive situation." (*Id*.)

Roxane also disputes the Government's characterization of the 1995 and 1997 Oramorph SR Marketing Memos. Roxane incorporates its Responses to ¶¶ 91 and 92. The Memos refer to third-party reimbursement generally, not government payors specifically, and the "spread" referenced in the documents refers to the difference between AWP and WAC, not AWP and acquisition cost or WAC and acquisition cost as the Government implies. (Fauci Ex. 87, 3/30/95 Marketing Memo #12; Fauci Ex. 88, 1/31/97 Marketing Memo #1) In addition, the larger "spread" vis-à-vis MS Contin between the AWP and WAC for Oramorph SR resulted from Roxane's lower WAC, not a higher AWP. Indeed, Roxane's AWP for Oramorph SR was generally less than MS Contin. (Tab 259, 8/5/08 Shaffer Dep. 392-93) Further, the documents cited by the Government pertain to a third-party reimbursement methodology based on a percent off of the "spread" between AWP and WAC; this methodology is not used by Medicare or Medicaid programs. (Fauci Ex. 87, 3/30/95 Marketing Memo #2; Fauci Ex. 88, 1/31/97 Marketing Memo #1) As such, this fact is not material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

Moreover, the Government references no testimony that Roxane's sales force ever used the points in Mr. Via's draft, non-final, internal memos when marketing Oramorph SR to customers. On the contrary, the testimony demonstrates that Roxane marketed Oramorph SR based on its price advantage over competitive products – Oramorph was priced 30-40% less than MS Contin – and the product's efficacy in treating certain therapeutic indications. (Tab 258, 5/21/08 Shaffer Dep. 89-94, 143, 150; Tab 259, 8/5/08 Shaffer Dep. 390-91) Roxane did not market Oramorph SR to pharmacies on the basis of increased Medicare or Medicaid reimbursement. (Tab 269, 10/18/05 Via Dep. 40-41, 51-54; Tab 258, 5/21/08 Shaffer Dep. 94-95; Tab 259, 8/5/08 Shaffer Dep. 388-92) In fact, Roxane marketed Oramorph SR primarily to physicians and hospice providers. (Tab 258, 5/21/08 Shaffer Dep. 54-55; Tab 259, 8/5/08 Shaffer Dep. 385-88) The Roxane sales force therefore had no incentive to market any "spread" because physicians are not reimbursed by state Medicaid programs for dispensing Oramorph SR. (Tab 258, 5/21/08 Shaffer Dep. 54-55, 89-91; Tab 259, 8/5/08 Shaffer Dep. 385-88)

In addition, Roxane's corporate representative testified that Roxane competed on contract price, and it was not Roxane's general practice to concern itself with the spread except in the "exceptional case" where it was brought to their attention that Roxane's AWPs were out of line with the norm. (Tab 276, 5/9/07 Waterer Dep. 103-04)

Q. Has Roxane ever concerned itself with the spread as it relates to the pharmacists' reimbursement?

A. If there was an exceptional instance where our pricing was out of line – I think I talked about, I believe it was Furosemide – in an exceptional case where it was brought to our attention, we might take steps to bring ourselves into the average or norm of what everybody else is doing. But in the industry, most everybody's pricing is set very similar so that the spread issue isn't something that generally comes up. If everybody's pricing is in the same average area, you're competing on the contract price. That's generally what occurs in the negotiation.

Q. So it's your testimony that Roxane has never concerned itself with the competitor's price and tried to market the spread to gain market share away from that competitor?

A. It – again, on a very rare instance, there may have been something that had to do with the difference in AWPs. It would not be our general practice. It would be a very rare occasion.

(*Id.*)

In addition, Roxane disputes the materiality of this alleged fact to the Government's Medicare claims against Roxane. Because Medicare reimbursed providers for generic drugs based on the median generic AWP, individual manufacturers' AWPs were irrelevant as providers received the same Medicare reimbursement regardless of which manufacturer's product they purchased. Therefore, there was no incentive for manufacturers to "market the spread" based on higher AWP prices. (Tab 254, 5/12/09 Scott Morton Dep. 185-86; Tab 255, 5/13/09 Scott Morton Dep. 321-22, 326; Tab 279, 5/21/09 Williams Dep. 280-81)

109. For example, a National Accounts Monthly Report from May 1998 describes a promotion related to Oramorph SR, and notes that Colin Carr-Hall (then a National Account Manager) "will forward a full package of membership and contract pricing/AWP spread benefits for inside sales to capitalize on." (Fauci Exhibit 65 (12/12/2008 Colin Carr-Hall Dep.), at 169:22 - 173:4; Fauci Exhibit 135, at RLI-AWP-00327756) Mr. Carr-Hall testified that he created an information package including a "spread analysis grid of the incremental profit pharmacists can realize" and that the purpose of this grid was to show pharmacists that they could make more money supplying Oramorph SR than the competitor's product. (Fauci Exhibit 65 (12/12/2008 Colin Carr-Hall Dep.), at 174:3 - 176:5; Fauci Exhibit 133, at BOEHOI 046682)

Roxane's Response: Undisputed that the documents and testimony contain the quoted

language. The Government's quotations, however, are selective and incomplete; the document and deposition testimony in their entirety are the best evidence of their respective content. The Government's proffered evidence refers to third-party reimbursement generally, not government payors specifically, and the "spread" referenced in the documents refers to the difference between AWP and WAC, not AWP and acquisition cost or WAC and acquisition cost as the Government implies. The larger "spread" vis-à-vis MS Contin between the AWP and WAC for Oramorph SR resulted from Roxane's lower WAC, not a higher AWP. Indeed, Roxane's AWP for Oramorph SR was generally less than MS Contin. (Tab 259, 8/5/08 Shaffer Dep. 392-93) As such, this fact is not material to the Government's motion for summaryjudgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

In addition, the Government references no testimony that Roxane's sales force ever used the "spread analysis grid" when marketing Oramorph SR to customers. On the contrary, the testimony demonstrates that Roxane marketed Oramorph SR based on its price advantage over competitive products – Oramorph was priced 30-40% less than MS Contin – and the product's efficacy in treating certain therapeutic indications. (Tab 258, 5/21/08 Shaffer Dep. 89-94, 143, 150; Tab 259, 8/5/08 Shaffer Dep. 390-91) Roxane did not market Oramorph SR to pharmacies on the basis of increased Medicare or Medicaid reimbursement. (Tab 269, 10/18/05 Via Dep. 40-41, 51-54; Tab 258, 5/21/08 Shaffer Dep. 94-95; Tab 259, 8/5/08 Shaffer Dep. 388-92) In fact, Roxane marketed Oramorph SR primarily to physicians and hospice providers. (Tab 258, 5/21/08 Shaffer Dep. 54-55; Tab 259, 8/5/08 Shaffer Dep. 385-88) The Roxane sales force therefore had no incentive to market any "spread" because physicians are not reimbursed by state Medicaid programs for dispensing Oramorph SR. (Tab 258, 5/21/08 Shaffer Dep. 54-55, 89-91; Tab 259, 8/5/08 Shaffer Dep. 385-88)

Roxane also disputes that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane as the alleged facts did not occur during the timeframe relevant to the Government's claims. The Government's cited document is dated 1998 and the Government's Oramorph SR claims are limited to 1999-2001. (US Cons. Memo re Roxane at 13 n.11) Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to Oramorph SR. (US Cons. Memo re Roxane at 13 n.11) *See* Local Rule 56.1; *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1.

Roxane further disputes that the alleged fact is material to the Government's Medicare claims against Roxane because Medicare reimbursed providers for generic drugs based on the median generic AWP, and thus individual manufacturers' AWPs were irrelevant as providers received the same Medicare reimbursement regardless of which manufacturer's product they purchased. Therefore there is no incentive for manufacturers to "market the spread" based on higher AWP prices. (Tab 254, 5/12/09 Scott Morton Dep. 185-86; Tab 255, 5/13/09 Scott

Morton Dep. 321-22, 326; Tab 279, 5/21/09 Williams Dep. 280-81)

110. Although Ms. Waterer testified in 2001 that she wouldn't "know how to begin to market a spread," (see Fauci Exhibit 20 (10/24/2004 Judith Waterer Dep.), at 180:20 - 180:25) the evidence establishes that Ms. Waterer was aware that sales representatives promoted "spreads" as a reason to buy Roxane's products and, moreover, that Ms. Waterer trained sales personnel how to do so. (*See*, *e.g.*, Fauci Exhibit 27 (5/9/2007 Judith Waterer 30(b)(6) Dep.), at 104:1 - 105:19) For example, in a September 3, 1997 email, Ms. Waterer noted that sales representatives were emphasizing reimbursement advantages to customers when promoting a drug called meperidine:

> What will it take for us to get the meperidine?? . . . Our WAC is just about their dead net acquisition price from Barr already but our AWP' s [sic] are higher than Barr's. This make our product more profitable for the pharmacies to sell - Not MAC'd yet!!! At similar pricing, we'll be preferred by the pharmacy - a fact our reps are not forgetting to mention!

(Fauci Exhibit 108) Likewise, according to an "Inside Sales Department November 1997 Monthly Report," Roxane ran a "mini-pilot on selling Azathioprine and Hydroxyurea using the spread between WAC and AWP." (Fauci Exhibit 109, at BOEH04556179) The report notes thatJudy Waterer trained sales representatives on how to do so. (*Id.*) The Report explains that the sales personnel "started out with WAC vs. AWP in [the] message, but as they learn of a[n] acquisition cost from their customer they are adjusting their message." (*Id.*)

Roxane's Response: Roxane disputes that this statement of fact is material to the Government's motion for summary judgment or its claims against Roxane because it relates to events that occurred outside the timeframe relevant to the Government's claims, and to drugs that are not at issue in this case (Fauci Ex. 108, 9/3/97 Swartz E-mail to Feldman (regarding meperidine, a drug not at issue in this case); Fauci Ex. 109, November 1997 Inside Sales Dept. Monthly Report (regarding hydroxyurea, a drug not at issue in this case, and azathioprine in 1997, a time period for which azathioprine is not at issue)) *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

Disputed that "Ms. Waterer was aware that sales representatives promoted 'spreads' as a

reason to buy Roxane's products" and disputed that "Ms. Waterer trained sales personnel how to do so." This alleged fact is not supported by the Government's cited testimony. Ms. Waterer testified that Roxane competed on contract price, and it was not Roxane's general practice to concern itself with the spread except in the "exceptional case" where it was brought to their attention that Roxane's AWPs were out of line with the norm. (Tab 276, 5/9/07 Waterer Dep. 103-04)

> Q. Has Roxane ever concerned itself with the spread as it relates to the pharmacists' reimbursement?
>
> A. If there was an exceptional instance where our pricing was out of line – I think I talked about, I believe it was Furosemide – in an exceptional case where it was brought to our attention, we might take steps to bring ourselves into the average or norm of what everybody else is doing. But in the industry, most everybody's pricing is set very similar so that the spread issue isn't something that generally comes up. If everybody's pricing is in the same average area, you're competing on the contract price. That's generally what occurs in the negotiation.
>
> Q. So it's your testimony that Roxane has never concerned itself with the competitor's price and tried to market the spread to gain market share away from that competitor?
>
> A. It – again, on a very rare instance, there may have been something that had to do with the difference in AWPs. It would not be our general practice. It would be a very rare occasion.

(*Id.*) Ms. Waterer does not testify about training sales personnel.

Undisputed that the Monthly Report contains the quoted language. The Government's quotations, however, are selective, incomplete, and misleading; the document and testimony in its entirety is the best evidence of its content. Roxane disputes that "using the spread between WAC and AWP" refers to marketing the spread between azathioprine's AWP and acquisition cost. Between 1996 and 1999 Roxane's azathioprine was the sole source generic for Imuran. Because it had the only generic product on the market, Roxane's goal was to provide incentives for customers to switch from the brand Imuran to its generic azathioprine (Tab 253, 1/8/09 Russillo Dep. 128, 131), a goal that the CMS itself just recently stated justified AWP to acquisition costs spreads as high as 73%:

> The Report also found that the percentage differences between Part D payments and drug acquisition costs were more than nine times higher for generic drugs than for brand-name drugs. Clinically appropriate generic prescribing is one of the key ways in which the Part D program is able to provide high quality coverage at a

> reasonable cost to both beneficiaries and the government. We fully encourage the use of generic drugs since their use provides good value to both the beneficiary and the taxpayer, and *we note that incentives are aligned to encourage promotion of generics by community pharmacies*.

(Tab 126, January 2008 OIG Report, at 6 and p. 1 of App. G) (emphasis added) Roxane provided those incentives by offering a lower contract/WAC price for its generic. (*See* generally US Roxane SOF and Roxane Responses at ¶¶ 64-68)

Disputed that Ms. Waterer "noted that sales representatives were emphasizing reimbursement advantages to customers when promoting a drug called meperidine" in a September 3, 1997 email. The alleged fact is not supported by the Government's proffered evidence of Fauci Exhibit 108, in which the only email from Judy Waterer was dated July 16, 1997. Undisputed that Fauci Exhibit 108 contains the quoted language, except that Roxane disputes that the document uses the word "make" instead of "makes." (Fauci Ex. 108, 9/3/97 Swartz E-mail to Feldman) The Government's quotation, however, is incomplete and misleading, in light of testimony given by Ms. Waterer. Ms. Waterer explained that in the July 16, 1997 email, her question "What will it take for us to get the meperidine," referred to the bid price that Roxane would have to offer. (Tab 274, 4/1/03 Waterer Dep. 431) She testified that her mention of a higher AWP and more profitability for pharmacies, which "our reps are not forgetting to mention," was merely an "idea," and something that was "never implemented." (*Id.* at 452-53) She stated that "When I made a comment about what the reps are doing, I was unaware of what reps were doing . . . . [I]t never happened." (*Id.*) "It's not something that was ever implemented. I don't believe this ever went farther than the initial e-mail." (*Id.* at 438) In addition, Roxane disputes the materiality of this alleged fact to the Government's Medicare claims against Roxane. Because Medicare reimbursed providers for generic drugs based on the median generic AWP, individual manufacturers' AWPs were irrelevant as providers received the same Medicare reimbursement regardless of which manufacturers' product they purchased. Therefore, there was no incentive for manufacturers to "market the spread" based on higher AWP prices. (Tab 254, 5/12/09 Scott Morton Dep. 185-86; Tab 255, 5/13/09 Scott Morton Dep. 321-22, 326; Tab 279, 5/21/09 Williams Dep. 280-81) Also disputed that this fact is material to the Government's Medicare claims against Roxane because the United States does not intend to pursue damages for Medicare claims relating to azathioprine. (*See* US Cons. Memo re Roxane at 3, n.3).

UNITED STATES' REPLY: Roxane is being evasive. Plainly, Ms. Waterer's testimony that she wouldn't begin to market a spread, juxtaposed against evidence that she in fact knew how to do so (and even trained sales representatives how to do so), is material to the United States' claims. In any event, the evidence in question is dated 1997, a period *within* the

United States' damages period.

E. Roxane's Decision to Set Inflated AWPs Was Made With Knowledge That Medicare and Medicaid Programs Utilized AWPs in Setting Reimbursement

111. Roxane was familiar with the Medicare and Medicaid programs and regularly included information about Medicare and Medicaid reimbursement as part of its marketing documents. (*See*, *e.g.*, Fauci Exhibit 110 (November 1995 Interoffice Memorandum Regarding Medicare Regions); Fauci Exhibit 62)

Roxane's Response: Disputed. The alleged fact is not supported by the Government's proffered evidence. Fauci Exhibit 110 only addresses the issue of how many and which J-Codes are used in Medicare regions for reimbursement of Atrovent (a Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") product) versus compounded ipratropium bromide and does not indicate whether anyone at Roxane received or reviewed it. (Fauci Ex. 110, 11/14/95 Ashey Memo) Indeed, in paragraph 46, the Government acknowledges that this memo was put together by BIPI, not Roxane. (U.S. Roxane SOF at ¶ 46) Neither Fauci Exhibit 110 nor Fauci Exhibit 62 even mentions Medicaid, and neither one supports the proposition that Roxane "regularly included information about Medicare and Medicaid reimbursement as part of its marketing documents." (Fauci Ex. 110, 11/14/95 Ashey Memo; Fauci Ex. 62, 2/19/96 Dusek Marketing Memo) Roxane also incorporates by reference its responses to paragraphs 46 and 66 (discussing Fauci Ex. 62).

Furthermore, Roxane corporate representative testimony indicates that Roxane was not familiar with the specifics of the Medicare or Medicaid programs or the formulas used by the programs to reimburse prescription drugs. (Tab 278, 12/12/08 Waterer Dep. 30-31, 165, 189 ("I don't have enough information or knowledge about what the states are doing [for Medicaid reimbursement]. I sell products. I don't get reimbursed for products. So I don't have a lot of focus on reimbursement programs. . . .) ("I'm not real familiar with [Medicare]") ("Roxane did not track information about [] state Medicaid reimbursement methods."); Tab 276, 5/9/07 Waterer Dep. 45-46 (Roxane was not familiar with "estimate acquisition cost" term or regulation); 332-33 ("How Medicare reimbursement works and what individual state's percent roles and how pharmacies are reimbursed, it's not part of our institutional knowledge . . . ."); 397-98 ("in recent times, pursuant to this type of litigation, we have a general understanding that there's a variety of different formulas that states use tied to a variety of different mechanisms . . . . I'm not aware of the corporation having specific knowledge as to individual state's [sic] plans in any type of routine or usable format."))

In addition, Roxane disputes that this alleged fact is material to the Government's motion for summary judgment or its claims against Roxane because the evidence the Government cites in support of its alleged fact is outside of the timeframe relevant to the Government's claims. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the

material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

112. For example, on or around November 14, 1995, Joseph Ashey circulated a memorandum entitled "Medicare Regions & Atrovent Solution Reimbursement." (Fauci Exhibit 110) The memorandum enclosed a "copy of a map reflecting the territories and states within each of the 4 Medicare reimbursement regions." (*Id.*) The memorandum also specified various "reimbursement rules by region[.]" (*Id.*) Roxane verified and incorporated the information included in this memorandum into its marketing strategies for ipratropium bromide (the generic equivalent of Atrovent). Specifically, Mr. Pope (a consultant hired by Roxane to help with the launch of ipratropium bromide) updated this research and reported his findings to Roxane's then Director of Multi-source Marketing (Mr. Tupa). (*See supra* ¶¶ 46-47; *see also* Fauci Exhibit 33, at RLI-AWP-00299562)

Roxane's Response: Disputed that Joseph Ashey circulated a memorandum entitled "Medicare Regions & Atrovent Solution Reimbursement." This alleged fact is not supported by the Government's proffered evidence, because Fauci Exhibit 110 only indicates that the memorandum was "from" Joseph Ashey; it does not indicate that Ashey circulated it. Moreover, in paragraph 46, the Government acknowledges that the memorandum was not put together by Roxane, but by employees at BIPI.

Undisputed that Fauci Exhibit 110 contains the quoted language. The Government's quotations, however, are selective, incomplete, and misleading; the document in its entirety is the best evidence of its content. The memorandum only addresses the "reimbursement rules" regarding how many and which J-Codes are used in each Medicare region for reimbursement of Atrovent (a BIPI product) and compounded ipratropium bromide. The memo does not discuss AWP or the formula used for calculating Medicare reimbursement. As such, it is immaterial to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). Roxane disputes that it incorporated the information included in the Ashey memorandum into its marketing strategies for ipratropium bromide. This alleged fact is not supported by the Government's proffered evidence. Fauci Exhibit 33 at RLI-AWP-00299562 does state the Ashey's memo "appears to be correct," but does not state or show incorporation of the memo into any "marketing strategies." Roxane hereby incorporates its Responses to ¶¶ 46 and 47.

In addition, Roxane corporate representative testimony indicates that Roxane was not familiar with the specifics of the Medicare or Medicaid programs or the formulas used by the programs to reimburse prescription drugs. (Tab 278, 12/12/08 Waterer Dep. 30-31, 165, 189 ("I

don't have enough information or knowledge about what the states are doing [for Medicaid reimbursement]. I sell products. I don't get reimbursed for products. So I don't have a lot of focus on reimbursement programs. . . .) ("I'm not real familiar with [Medicare]") ("Roxane did not track information about [] state Medicaid reimbursement methods."); Tab 276, 5/9/07 Waterer Dep. 45-46 (Roxane was not familiar with "estimate acquisition cost" term or regulation); 332-33 ("How Medicare reimbursement works and what individual state's percent roles and how pharmacies are reimbursed, it's not part of our institutional knowledge . . . ."); 397-98 ("in recent times, pursuant to this type of litigation, we have a general understanding that there's a variety of different formulas that states use tied to a variety of different mechanisms . . . . I'm not aware of the corporation having specific knowledge as to individual state's [sic] plans in any type of routine or usable format."))

113. Roxane also included information about Medicare reimbursement in its marketing documents relating to the launch of azathioprine. (*See supra* paragraph 66) For example, a February 19, 1996 Marketing Memo references the Medicare reimbursement code for azathioprine, and encourages sales personnel to go over the "Medicare selling message." (Fauci Exhibit 62; Fauci Exhibit 111 (document entitled "Sales Strategy" and noting that "Roxane azathioprine, by virtue of its favorable pricing, has a distinct Medicare advantage") (emphasis in original))

Roxane's Response: Undisputed that the document contains the quoted language. Roxane disputes that these facts, which occurred in 1996, are material to the Government's motion for summary judgment or its claims against Roxane because they relate to events that occurred outside the timeframe relevant to the Government's claims, which do not begin until 1999 for azathioprine. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). Disputed that this fact is material to the Government's Medicare claims because the United States does not intend to pursue damages for Medicare claims relating to azathioprine. (*See* US Cons. Memo re Roxane at 3, n.3)

In addition, the Government's quotation is selective and incomplete; the document in its entirety is the best evidence of its content. Roxane hereby incorporates its response to Paragraph 66. The referenced memo simply recognizes that providers received the same Medicare reimbursement regardless of which manufacturer's product they purchased. (Fauci Ex. 62, 2/19/96 Dusek Marketing Memo; Fauci Ex. 111, Azathioprine Sales Strategy) Therefore, there is no incentive for manufacturers to "market the spread" based on higher AWP prices. (Tab 254, 5/12/09 Scott Morton Dep. 185-86; Tab 255, 5/13/09 Scott Morton Dep. 321-22, 326; Tab 279, 5/21/09 Williams Dep. 280-81) In the case of Roxane's azathioprine, the "favorable pricing" was its lower WAC price. (Fauci Ex. 111, Azathioprine Sales Strategy) Roxane set its pricing to encourage conversion from the brand to its generic (Tab 253, 1/8/09 Russillo Dep. 128, 131), a goal that the CMS itself just recently stated justified AWP to acquisition costs spreads as high as

73%:

> The report also found that the percentage differences between Part D payments and drug acquisition costs were more than nine times higher for generic drugs than for brand-name drugs. Clinically appropriate generic prescribing is one of the key ways in which the Part D program is able to provide high quality coverage at a reasonable cost to both beneficiaries and the government. We fully encourage the use of generic drugs since their use provides good value to both the beneficiary and the taxpayer, and *we note that incentives are aligned to encourage promotion of generics by community pharmacies*.

(Tab 126, January 2008 OIG Report at 6 and p. 1 of App. G) (emphasis added)

In addition, Roxane corporate representative testimony indicates that Roxane was not familiar with the specifics of the Medicare or Medicaid programs or the formulas used by the programs to reimburse prescription drugs. (Tab 278, 12/12/08 Waterer Dep. 30-31, 165, 189 ("I don't have enough information or knowledge about what the states are doing [for Medicaid reimbursement]. I sell products. I don't get reimbursed for products. So I don't have a lot of focus on reimbursement programs. . . .) ("I'm not real familiar with [Medicare]") ("Roxane did not track information about [] state Medicaid reimbursement methods."); Tab 276, 5/9/07 Waterer Dep. 45-46 (Roxane was not familiar with "estimate acquisition cost" term or regulation); 332-33 ("How Medicare reimbursement works and what individual state's percent roles and how pharmacies are reimbursed, it's not part of our institutional knowledge . . . ."); 397-98 ("in recent times, pursuant to this type of litigation, we have a general understanding that there's a variety of different formulas that states use tied to a variety of different mechanisms . . . . I'm not aware of the corporation having specific knowledge as to individual state's [sic] plans in any type of routine or usable format."))

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 50 (explaining that the report referenced at Tab 126 does *not* provide evidence to support a finding that CMS ever approved of a drug manufacturers' reporting inflated AWPs for any drugs reimbursed by Medicare or Medicaid; the report referenced by Roxane relates *only* to the Medicare Part D Program, which does *not* involve reimbursement of claims by the government).

114. Roxane regarded inclusion on state Medicaid formularies as important to the success of a product. (*See*, *e.g.*, Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 244:19 – 244:22; Fauci Exhibit 112 (6/25/2002 Richard Feldman Dep.),

at 89:2 - 89:6; Fauci Exhibit 113 (12/3/2004 Jim King Dep.), at 125:1 - 126:9; Fauci Exhibit 65 (12/12/2008 Colin Carr Hall Dep.), 247:9 - 248:10; Fauci Exhibit 114 (12/16/2008 Fred Duy Dep.), at 188:6 - 189:3) 131

Roxane's Response: Undisputed.

115. Roxane often referenced Medicaid programs as part of its marketing documents. For example, the launch plan for Roxane's 15/30 mg Roxicodone tablets included a "Medicaid Reimbursement Plan" outlining steps for notifying state Medicaid programs of Roxicodone's availability and for submitting requests that the products be added to state formularies. (Fauci Exhibit 94, at Shaffer 001490) Mr. Sykora (then the Director of National Accounts) prepared a series of slides to present to Roxane's palliative care sales force in anticipation of the launch of Roxane's 15/30 mg Roxicodone tablets. (Fauci Exhibit 11 (12/4/2008 Robert Sykora Dep.), at 133:7 - 135:13) One slide, entitled "Reimbursement," identified Medicaid as one of three patient payment types for Roxicodone (Fauci Exhibit 99, at BOEHO1301724) and another slide noted that pharmacies were paid by Medicaid at either a "Maximum Allowable Cost (MAC)" or "AWP less %." (*Id.*, at BOEHO1301725)

Roxane's Response: Disputed that "Roxane often referenced Medicaid programs as part of its marketing documents." The Government's proffered evidence does not support this alleged fact. The Government cites three references to Medicaid that all relate to a single Subject Drug, Roxicodone, at one point in time. Moreover, two of the references to Medicaid relate to issues – formulary status and Medicaid as a payment type – that are not relevant to the Government's motion for summary judgment or its claims against Roxane. In addition, Roxane objects to the Government's use of the term "marketing documents" as vague and ambiguous and to the extent it implies documents that Roxane sent to customers to market its drugs, as the Government only cites internal strategic documents and memoranda.

Undisputed that slides existed for a presentation Mr. Sykora was scheduled to give to Roxane's palliative care sales force, but disputed that Mr. Sykora prepared those slides. This alleged fact is not supported by the Government's evidence. The deposition testimony cited by the Government only states that Mr. Sykora was scheduled to give, and gave, the presentation, not that he prepared the slides for that presentation. (Fauci Ex. 11, 12/4/08 Sykora Dep. 133-35) In fact, Mr. Sykora testified that an outside consulting agency likely prepared the slides with some input from him. (Tab 263, 12/4/08 Sykora Dep. 137-38)

Undisputed that the slide entitled "Reimbursement" listed Medicaid as one of three patient payment types for Roxicodone, and that another slide indicated that two options for state Medicaid programs are "Maximum Allowable Cost (MAC)" and "AWP less % for brand and some generics." The Government's statements, however, are selective and incomplete; the full document is the best evidence of its content. Roxane incorporates by reference its response to

Paragraphs 102 and 103, *infra*, which explain the purpose and background relating to Mr. Sykora's referenced presentation to the palliative care sales force. Moreover, the fact that Roxane had to prepare a presentation in 2000 to explain to its sales force how Medicaid programs reimbursed for drugs is consistent with the testimony of Roxane witnesses that Roxane was not familiar with the specifics of the Medicaid program or the formulas used by the state programs to reimburse prescription drugs. (Tab 278, 12/12/08 Waterer Dep. 30-31, 165, 189 ("I don't have enough information or knowledge about what the states are doing [for Medicaid reimbursement]. I sell products. I don't get reimbursed for products. So I don't have a lot of focus on reimbursement programs. . . .) ("I'm not real familiar with [Medicare]") ("Roxane did not track information about [] state Medicaid reimbursement methods."); Tab 276, 5/9/07 Waterer Dep. 45-46 (Roxane was not familiar with "estimate acquisition cost" term or regulation); 397-98 ("in recent times, pursuant to this type of litigation, we have a general understanding that there's a variety of different formulas that states use tied to a variety of different mechanisms . . . . I'm not aware of the corporation having specific knowledge as to individual state's [sic] plans in any type of routine or usable format.")))

116. Roxane was aware that Medicare and many state Medicaid programs utilized AWPs in setting reimbursement, and that many third party payors, including Medicaid agencies, used First Data Bank to obtain AWPs. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 93:16 - 93:22, 129:11 - 130:1, 244:14 - 245:19; Fauci Exhibit 19 (11/30/2005 Leslie Paoletti Dep.), at 50:10 - 50:19; Fauci Exhibit 112 (6/25/2002 Richard Feldman Dep.), at 88:2 - 88:12; Fauci Exhibit 99, at BOEHO1301724 - BOEHO1301725)

Roxane's Response: Undisputed that certain Roxane employees were aware or became aware at various times that third party payors, including certain government programs, utilized AWP less a percentage in setting reimbursement and that AWPs were obtained from First Databank for that purpose. However, Roxane's corporate representative testified that Roxane's knowledge of the use of AWP was mostly related to third party payors and that its awareness of its use in Government programs primarily came through the various investigations and litigations regarding AWP:

Q. Well, you know that state Medicaid agencies consider AWP when they reimburse, correct?

A. I've become aware of that, yes.

Q. What do you mean when you say you've become aware of that?

A. This litigation in various forms has been going on for many, many, many years. And because of it, I've learned a lot of things that I wouldn't normally need to know for my day-to-day activities.

Q. Didn't you know back as early as 1996 that state Medicaid agencies reimbursed based on AWP?

A. I don't know if I knew specifically state. I would say that I had a general awareness that private-party insurers, that AWP may be of – something that they tied reimbursement to. I don't recall having specific knowledge as to an individual state or a program.

Q. But you've known since as early as 1996 when you started with Roxane that the AWP that Roxane reported was relied upon by certain payors when they reimbursed, correct?

A. In a broad general sense, that's – as I said before, aware that certain payors, primarily private payors, have some formulas that tied to that, yes.

(Tab 276, 5/9/07 Waterer Dep. 76-77) In addition, Roxane corporate representative testimony indicates that Roxane was not familiar with the specifics of the Medicare or Medicaid programs or the formulas used by the programs to reimburse prescription drugs. (Tab 278, 12/12/08 Waterer Dep. 30-31, 165, 189 ("I don't have enough information or knowledge about what the states are doing [for Medicaid reimbursement]. I sell products. I don't get reimbursed for products. So I don't have a lot of focus on reimbursement programs. . . .) ("I'm not real familiar with [Medicare]") ("Roxane did not track information about [] state Medicaid reimbursement methods."); Tab 276, 5/9/07 Waterer Dep. 45-46 (Roxane was not familiar with "estimate acquisition cost" term or regulation); 332-33 ("How Medicare reimbursement works and what individual state's percent roles and how pharmacies are reimbursed, it's not part of our institutional knowledge . . . ."); 397-98 ("in recent times, pursuant to this type of litigation, we have a general understanding that there's a variety of different formulas that states use tied to a variety of different mechanisms . . . . I'm not aware of the corporation having specific knowledge as to individual state's [sic] plans in any type of routine or usable format."))

117. For example, in April 2000, Mr. Rowenhorst (then "Reimbursement Manager") circulated an email under the heading "Medicare reimbursement of Combivent UDV." (Fauci Exhibit 115) The email summarized Mr. Rowenhorst's "findings," including that Medicare reimbursement "is based on the AWP." (*Id.*; *see also* Fauci Exhibit 116) Mr. Rowenhorst also specified that "generic products" were reimbursed at the "median of all generic AWPs" and he included examples of what Medicare would reimburse for certain drugs and dosages. (*Id.*)

Roxane's Response: Disputed that Mr. Rowenhurst was the "Reimbursement Manger" as this alleged fact is not supported by the Government's proffered evidence. Undisputed that the document contains the quoted language. The Government's quotations, however, are incomplete, selective, and misleading; the document in its entirety is the best evidence of its content. This document was drafted by a BIPI employee, was sent to only BIPI employees and is related to a

BIPI branded product, Combivent UDV. There is no evidence indicating that any Roxane employee received or reviewed the document or had knowledge of or understood the information in the document. As this fact does not relate to Roxane or a Subject Drug, it is not material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). Moreover, the fact that BIPI had to research basic information regarding Medicare reimbursement in 2000 demonstrates how BIPI, like Roxane, was not familiar with the specifics of the Medicare or Medicaid programs or the formulas used by the programs to reimburse prescription drugs. Also, Roxane notes that Mr. Rowenhorst did not state that "'generic products' were reimbursed at the 'median of all generic AWPs,'" but rather, that "[g]eneric products are reimbursed at ***80% of*** the median of all generic AWPs." (Fauci Exhibit 115, 4/12/00 Rowenhorst E-mail to Garofalo (emphasis added))

118. Roxane was also aware that, at various times, First Data Bank defined AWP as follows:

> AWP is the average wholesale price. That is, AWP is the average of the prices charged by the national drug wholesalers for a given product (NDC). The operative word is average. AWP was developed to provide a price which all parties could agree upon for electronic pricing to be possible.

(Fauci Exhibit 117; *see also* Fauci Exhibit 101 (Reimbursement Background Memorandum), at Paoletti 20751-52 (stating that AWPs "were meant to reflect an average of suggested list prices that wholesalers charged various customer outlets."))

Roxane's Response: Disputed that Roxane was aware that First DataBank defined AWP in accordance with the quoted language above. This alleged fact is not supported by the Government's proffered evidence, which only indicates that the quoted language was in an attachment to an e-mail that was sent to Richard Feldman. (Fauci Ex. 117, 3/27/00 Morgan E-mail to Feldman) The Government does not cite to any document or deposition testimony indicating that anyone at Roxane received or reviewed the e-mail or its attachment, or understood from it that First DataBank defined AWP as the quoted language above. To the contrary, Roxane has understood AWP to be a reference point generally tied to the brand and not an actual average of drug transaction prices. (Roxane SOF at ¶¶ 99-100) In an internal presentation regarding the launch of Roxicodone given near the same time the Reimbursement Background Memorandum the Government cites was circulated, Roxane stated that AWP was defined as "[a]n arbitrary price attributed to a product." (Fauci Ex. 99, Distribution Workshop Slide-Show at BOEH01301724) Roxane's understanding is consistent with testimony provided by First

DataBank. Patricia Kay Morgan, former Manager of Editorial Services at First DataBank, testified that First DataBank did not believe AWP to be a transaction price, and instead believed it to be a benchmark used for reimbursement purposes. (Tab 244, 11/30/07 Morgan Dep. 33-35, 50) Indeed, First DataBank referred to AWP as "Ain't What's Paid." (*Id.* at 34-35) First DataBank believed it was "not a secret in the industry that contract prices were lower than AWPs." (*Id.* at 36-37)

Moreover, while Roxane does not dispute that the Reimbursement Background document, Fauci Exhibit 101, contains the quoted language, the Government's quotation is incomplete, selective, and misleading. The Government's quotes are taken from a section of the document explaining *historical* pricing and reimbursement practices. (Fauci Ex. 101, 9/8/00 Reimbursement Background at 3-4) The same document later defines AWP as "Neither an average price nor a price charged by wholesalers, this figure is a vestige of earlier times." (*Id.* at 8) Roxane further disputes any implication that a Roxane employee authored this document or that Roxane knew, adopted or agreed with any information contained in the document. Indeed, the Roxane employee who distributed the memorandum to other Roxane employees repeatedly testified that he did not write the document, did not have an understanding at the time of what certain statement in the document meant, was not familiar with the information in the document (including the quotes referenced by the Government) and did not agree with certain statements in the document. (Tab 258, 5/21/08 Shaffer Dep. 247-48, 252-53, 257-259, 261, 263)

F. Roxane Took Steps To Ensure That Only Its AWPs Were Published For Certain of The Subject Drugs

1. Roxane Stopped Reporting New WACs for Its Multi-Source Products Contemporaneously with Its Decision to Lower WACs for Over 200 Products

119. Beginning in or around November 1997, Roxane began to evaluate the steps necessary "to reduce WAC pricing across the board to wholesalers[.]" (Fauci Exhibit 118; Fauci Exhibit 119; Fauci Exhibit 12 (11/17/2004 Richard Feldman Dep.), at 113:4 - 113:10)

Roxane's Response: Undisputed.

120. According to a memorandum sent by Ms. Waterer to her then supervisor, Mr. Tupa, Roxane lowered WACs for over two hundred multi-source products in late 1997 and early 1998 to bring them "into line with the true prices that retail drug stores actually pay for the products." (Fauci Exhibit 120 (March 13, 1998 Inter-office Memorandum), at Rox 03041)

Roxane's Response: Undisputed that the memorandum cited as Fauci Exhibit 120 indicates that Roxane planned to lower WACs for over two hundred SKUs effective March 16,

1998. Undisputed that one of the reasons that Roxane planned to adjust its WAC pricing was to bring them "into line with the true prices that retail drug stores actually pay for the products." Disputed that this reason was the only reason. For example, another reason Roxane adjusted its WAC pricing was because wholesalers were demanding that Roxane switch from 1% to 2% prompt payment terms in accordance with industry standard, and accordingly the amount Roxane would pay in prompt 138 pay terms "would double if we didn't lower our prices." (Fauci Ex. 120, 3/3/98 Tupa Memo to Waterer at Rox 03041; Tab 276, 5/11/07 Waterer Dep. 630-32)

121. Ms. Waterer identified at least two rationales for implementing the WAC change. (*Id*.) First, prior to the change, Roxane's WACs were "as much as 8 to 10 times" higher than products' "actual retail value." (Fauci Exhibit 120, at Rox 03041) Wholesalers had expressed "extreme displeasure" at having to be "rebated, or charged back as much as 80%-90% of the original purchase price." (*Id*.; *see also* Fauci Exhibit 5 (1/31/2003 Edward Tupa Dep.), at 161:2 - 162: 16) Second, Roxane paid certain rebates to customers as percentages of WAC. Because Roxane's WACs were "as much as 8 to 10 times" higher than some products' "actual retail value," the rebates paid by Roxane often were disproportionately large in relation to the selling price. (Fauci Exhibit 120, at Rox 0304; Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 513:11 - 515:5)

Roxane's Response: Undisputed that Ms. Waterer identified at least two rationales for implementing the March 1998 WAC change. Undisputed that one reason for the WAC change was because Roxane's WACs had been as much as 8 to 10 times higher than the products' actual retail value and the wholesalers had expressed extreme displeasure at carrying the difference in price after it sold the product to a pharmacy and before it received a charge-back. (Fauci Ex. 120, 3/3/98 Tupa Memo to Waterer at Rox 03041; Tab 276, 5/11/07 Waterer Dep. 630-32). Undisputed that Roxane paid wholesalers prompt payment terms that were calculated as a percentage of WAC. (*Id.*) Disputed that such terms were called "rebates" as that fact is not supported by the Government's proffered evidence. Undisputed that another reason for the WAC change was because wholesalers were demanding that Roxane switch from 1% to 2% prompt payment terms in accordance with industry standard, and accordingly the amount Roxane would pay in prompt pay terms "would double if we didn't lower our prices." (Fauci Ex. 120, 3/3/08 Tupa Memo to Waterer at Rox 03041; Tab 276, 5/11/07 Waterer Dep. 630-32)

122. On or about November 24, 1997, Roxane held a "Program Implementation Meeting" to discuss, among other things, the proposed WAC adjustment. (Fauci Exhibit 118) Prior to implementing WAC adjustments to its "full line" of multi-source products, Roxane elected to lower the WACs for its ipratropium bromide and ranitidine products as a "trial" or "pilot" run. (Fauci Exhibit 118; Fauci Exhibit 120; Fauci Exhibit 121; Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 500:4 - 500:9, 505:17 - 505:23)

Roxane's Response: Undisputed.

123. On or about December 1, 1997, Roxane lowered the WACs for two ipratropium bromide and three ranitidine products. (*See supra* ¶ 55; *see also* Fauci Exhibit 47) Roxane personnel referred to this as the "Baby WAC" adjustment. (Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 503:17 - 504:4)

Roxane's Response: Undisputed that the document cited as Fauci Exhibit 47 indicates that on or about December 1, 1997, Roxane lowered the WACs for two ipratropium bromide NDCs and three ranitidine NDCs. Disputed that this alleged fact as it relates to ranitidine is material to the Government's motion for summary judgment or its claims against Roxane because it does not relate to one of the Subject Drugs at issue in this case. Undisputed that Roxane personnel referred to the WAC adjustment on ipratropium bromide and ranitidine on or around December 1, 1997 as the "Baby WAC" adjustment.

124. On or before December 8, 1997 (one week after reducing the WACs for its ipratropium bromide and ranitidine products), Roxane decided to stop reporting WACs for its multi-source products to First Data Bank. (Fauci Exhibit 48) A December 8, 1998 email sent by Cheri Mayhew (then Roxane's "Promotional Materials Administrator") to Judy Waterer stated as follows:

> I discussed with Kathy from First Data Bank, that we no longer want to publish or supply to them our WAC prices. It's okay with them that we do not supply the WAC price. However, there are approximately 10 states that use WAC for stateMedicaid, instead of the AWP. She informed me that these states will use the last published WAC to determine state Medicaid for those states. So if we decide not to supply them with WAC for price increases they will use old pricing. She did not address new products.

(*Id.*)

Roxane's Response: Disputed that on or before December 8, 1997, "Roxane decided to stop reporting WACs for its multi-source products to First DataBank." The Government's proffered evidence does not support this fact. Rather, Fauci Exhibit 48 dated December 8, 1997 merely shows that Roxane was *considering* a decision to stop reporting WACs at that time, stating "if we decide not to supply them with WAC." Disputed that Fauci Exhibit 48 is a December 8, 1998 email. Rather, Fauci Exhibit 48 is an email from December 8, 1997. Undisputed that Fauci Exhibit 48 contains the text as indicated above. Disputed that Cheri Mayhew was "then Roxane's 'Promotional Materials Administrator,'" as the Government's proffered evidence does not support this alleged fact.

Roxane further states that it stopped reporting WACs for its multi-source products because it was not industry practice to do so, and because WAC was and is an actual transaction price for its drugs. (*See* Roxane SOF at ¶ 114) Disputed that Roxane's decision to stop reporting WAC is material to the Government's Medicare claims against Roxane because Medicare did not reimburse on the basis of WAC. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

125. When Roxane decided to stop reporting WACs in or around December 1997, plans were already in place to reduce the WACs for over 200 multi-source products. (Fauci Exhibit 118; Fauci Exhibit 119; Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 504:18 – 506:5) Roxane knew that if it did not report its new (reduced) WACs, First Data Bank would continue to report Roxane's last published (and higher) WACs. (Fauci Exhibit 48; Fauci Exhibit 27 (5/9/2007 Judith Waterer 30(b)(6) Dep.), at 213:13 - 214:5)

Roxane's Response: Undisputed that when Roxane decided to stop reporting WAC in or around December 1997 or early 1998, plans were already in place to reduce the WACs for over dozens of SKUs. Disputed that Roxane knew that if it did not report its new WACs, First Data Bank would continue to report Roxane's last published WACs as that fact is not supported by the Government's proffered evidence. The Government's cited evidence, Fauci Exhibits 48 and 27, only indicate that Roxane was informed by Kathy at First Data Bank that the States that use WAC for State Medicaid would use the last published WAC to determine State Medicaid for those States. The Government's cited evidence does not indicate that Roxane knew that it would be unsuccessful in getting First Data Bank to remove all published WACs for Roxane until the end of 1999. Roxane disputes that this fact is material to the Government's Medicare claims because Medicare did not reimburse on the basis of WAC. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

126. Roxane implemented its "full line" WAC change in March 1998. (Fauci Exhibit 120; Fauci Exhibit 122) Customers were notified on March 13, 1998. (Fauci Exhibit 123) The WAC changes were effective March 16, 1998, and encompassed 266 products in total with the WACs decreasing for 220 products. (*Id.*; *see also* Fauci Exhibit 120) Of the Subject Drugs, WACs were decreased for diclofenac sodium, hydromorphone and sodium polystyrene sulfonate (in addition to the ipratropium bromide WAC reduction discussed *supra* at Paragraph 54-55). (*Id.*)

Roxane's Response: Undisputed that Roxane implemented a "full line" WAC change in

March 1998. Undisputed that the WAC changes were effective March 16, 1998 and encompassed 266 SKUs in total, with the WACs decreasing for 220 SKUs. Undisputed that Fauci 123 indicates that customers were notified on or around March 13, 1998. Undisputed that WACs were decreased for the diclofenac sodium, hydromorphone and sodium polystyrene sulfonate products at issue in this case.

127. Although Roxane reduced the WACs for over 200 products, Roxane did not lower any of the corresponding AWPs. (*Id*.; *see also* Fauci Exhibit 124; Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 518:15 - 519:5; Fauci Exhibit 27 (5/9/2007 Judith Waterer 30(b)(6) Dep.), at 148:3 - 148:12; Fauci Exhibit 72 (7/24/2007 Judith Waterer Dep.), at 761:10 - 761:21) For example, the March 1998 price changes lowered the WACs for two of Roxane's diclofenac sodium products (NDCs 00054-4221-25 and 00054-4222-25) from $40.45 to $28.06 and from $45.53 to $31.23, respectively. (Fauci Exhibit 123, at Rox Tx 14601) Roxane did not reduce the AWPs for these products (which remained $86.13 and $104.31, respectively). (*Id*.)

Roxane's Response: Undisputed that the cited documents indicate that Roxane did not lower any of the corresponding AWPs when it reduced the WACs for over 200 products during the March 1998 WAC change. Undisputed that Fauci Exhibit 123 indicates that the March 1998 price changes lowered the WACs for two of Roxane's diclofenac sodium products from $40.45 to $28.06 and from $45.53 to $31.23, respectively. Undisputed that Fauci Exhibit 123 indicates that Roxane did not reduce the AWPs for these two diclofenac sodium products (which remained $86.13 and $104.31, respectively).

128. On other occasions when Roxane *increased* WACs for products, personnel within Roxane's marketing department recommended corresponding AWP increases "in order to maintain the current spread." (Fauci Ex. 125)

Roxane's Response: Disputed. First Roxane disputes that this paragraph is material to the Government's motion for summary judgment or its claims against Roxane because there is no evidence the referenced document relates to a Subject Drug at issue in this case. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). Roxane also disputes that "[o]n other occasions when Roxane increased WACs for products, personnel within Roxane's marketing department recommended corresponding AWP increases 'in order to maintain the current spread.'" This alleged fact is not supported by the Government's proffered evidence, which only supports that on one occasion when Roxane increased WACs for its products, one person within Roxane's marketing department recommended corresponding AWP increases "in order to maintain the current spread." Moreover, the document indicates that "nearly all" the drugs to which this recommendation applied were "sole source generic items." (Fauci Ex. 125, 10/19/98 Paoletti

Memo to Waterer) As Ms. Waterer explained, in the unique situation where Roxane had a sole source generic "it was common for us when you're a sole source generic to tie your AWP to the brand's AWP. As a sole source generic, if the brand increased the price, we chose to go in tandem and increase ours as well. So we were following the lead of the brand." (Tab 277, 7/24/07 Waterer Dep. 771-72) Having the market's sole source generic provided Roxane the "opportunity when the brand increases the price because of the competitive dynamics to increase the price in tandem with the brand and still be offering a significant discount to the end use customer." (*Id.*)

129. In accord with its decision to stop reporting WACs for multi-source products, Roxane did not report the new (reduced) WACs announced on March 16, 1998 to First Data Bank. (Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 518:3 - 518:10; Fauci Exhibit 27 (5/9/2007 Roxane Dep.), at 153:20 - 154:23)

Roxane's Response: Undisputed, however Roxane objects to this alleged fact on the grounds that Roxane's decision to stop reporting WAC for multi-source products is immaterial to the Government's Medicare claims against Roxane because Medicare reimbursed based on median AWP, not WAC. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

130. In addition, while Roxane did not lower any AWPs as part of its March 16, 1998 price change, Roxane *did* raise AWPs for certain (primarily branded or branded generic) products. (Fauci Exhibit 123, at Rox TX 14601 (e.g., the AWPs for Roxane's codeine phosphate solution and codeine sulfate tablets increased); *see also* Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 503:3 - 503:24) Although the March 1998 WAC changes were not reported to First Data Bank, Roxane did report the AWP increases. (Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 502:3 - 502:22, 518:3 - 518:14)

Roxane's Response: Undisputed that Roxane did raise AWPs, as well as WACs, for certain products. Pursuant to Roxane's new policy and consistent with industry practice, Roxane reported the AWP changes but did not report the WAC changes. (*See* Roxane SOF at ¶ 114; Fauci Ex. 6, 4/1/03 Waterer Dep. 502)

131. Mr. Tupa testified that not publishing the new WACs had the effect of preventing state Medicaid programs from learning of Roxane's most current WACs. (Fauci Exhibit 5 (1/31/2003 Edward Tupa Dep.), at 180:19 - 181:3)

Roxane's Response: Disputed. The Government's proffered evidence does not support this alleged fact as phrased. In the testimony attached as Fauci Exhibit 5, Mr. Tupa agrees that, "if it's true" that approximately ten States use WAC for state Medicaid instead of AWP, then not

publishing the new WACs would have "the effect of preventing at least ten State Medicaids from learning of the WAC decrease." Also disputed that States could not have requested and received WAC prices from Roxane. For example, Roxane provided WAC information to Massachusetts at its request. (Tab 288, Gilmore Ex. 9, 6/24/99 McCoy Letter to Massachusetts Medicaid re Updated WAC and AWP for Lithium Carbonate) In addition, certain States have passed laws requiring manufacturers to provide WACs directly to State Medicaid programs, including Vermont and New Mexico. (Vt. Stat. Ann. Tit. 33 § 2010 (Vermont); N.M. Stat. § 27-2E-1 (New Mexico)

2. Roxane Subsequently Took Steps to Remove Its WAC Pricing From First Data Bank

132. On or about October 14, 1999, James Rowenhorst (then "Reimbursement Manager") sent an email notifying Ms. Waterer and Ms. Paoletti (then an assistant to Ms. Waterer) that he had spoken with the Florida Medicaid Department regarding a "reimbursement issue" on one of Roxane's products. (Fauci Exhibit 126) Specifically, Mr. Rowenhorst noted that the Florida Medicaid program had changed its method of reimbursement and was "now reimbursing the pharmacist at the lowest price in the First Data Bank System, be it AWP, WAC (WHN) or Direct, plus 7%." (*Id* .) Mr. Rowenhorst asked Ms. Paoletti to validate that Roxane's most current prices were entered into First Data Bank and to verify that Roxane's old WAC and Direct Prices were "removed or updated." (*Id*.)

Roxane's Response: Disputed that Mr. Rowenhorst was "then Reimbursement Manager" as the Government's proffered evidence does not support the alleged fact. Undisputed that the document contains the quoted language, except that Roxane disputes that the document contains the word "at" between "reimbursing the pharmacist" and "the lowest price in the First Data Bank System." (Fauci Ex. 126, 11/5/99 Paoletti Email to Waterer) The Government's quotations, however, are selective and incomplete; the document in its entirety is the best evidence of its content. Mr. Rowenhurst's e-mail relates to a reimbursement issue for lorazapam, a Roxane drug that is not at issue in this case. As such, this alleged fact is not material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

133. Ms. Paoletti subsequently attempted to have First Data Bank remove Roxane's WAC pricing from its database. (Fauci Exhibit 24 (11/9/2004 Leslie Paoletti Dep.), at 99:13 – 99:18) On or about October 20, 1999, Ms. Paoletti wrote a letter to First Data Bank, enclosing pricing corrections for Roxane's "Product Listing." (Fauci Exhibit 127) The cover letter to First Data Bank stated in relevant part:

> Thank you for the opportunity to provide First Data Bank with the most up to date product listing. Please note the corrections to pricing and discontinuations and remove inaccurate WAC pricing, where indicated. *Accurate WAC pricing will not be furnished*, as it is company policy not publish [sic] this information.

(*Id*.) (emphasis supplied) On the first page of Roxane's product listing (enclosed with the October 20, 1999 letter), Ms. Paoletti wrote "NP = Not Published." (*Id*.; *see also* Fauci Exhibit 19 (11/30/2005 Leslie Paoletti Dep.), at 127:19 - 128:7) Ms. Paoletti crossed out the "WHLNET" (or WAC) price for approximately 200 products on Roxane's product listing, and noted "NP" for each of these products instead. (Fauci Exhibit 127) Ms. Paoletti testified that where the WACs were not crossed out, it was likely because the product was either discontinued or part of Roxane's "branded" product line. (Fauci Exhibit 19 (l1/30/2005 Leslie Paoletti Dep.), at 128:11 - 128:17)

Roxane's Response: Undisputed that the documents and deposition testimony contain the quoted language. The Government's quotations, however, are selective and incomplete; the documents and full deposition testimony in their entirety are the best evidence of their respective content. Undisputed that Ms. Paoletti attempted to have First Data Bank remove Roxane's old and inaccurate WAC pricing from its database. (Fauci Ex. 24, 11/9/04 Paoletti Dep. 99) However, Roxane disputes the implication that Ms. Paoletti only attempted to have First Data Bank remove Roxane's WAC pricing from its database subsequent to October 14, 1999, as such implication is not supported by the Government's proffered evidence. There is nothing in the Government's proferred evidence to indicate whether or how long Ms. Paoletti had already been trying to get First Data Bank to remove Roxane's WACs. Indeed, the evidence indicates that Roxane attempted on numerous occasions to have First Databank remove the outdated WAC pricing. (Tab 275, 11/28/05 Waterer Dep. 239-42 ("[W]e had one heck of a time getting First Data Bank to report correct information. We went through their information and repeatedly told them that they were not reporting the correct information . . . . we had been consulting with our legal department to find out whether or not we would have to pursue legal remedy to get them to stop reporting false information . . . . What I took out of this was, here's another example that we have to go back to First Data Bank yet again. We have repeatedly given them the information, but now it's getting to the point where it's becoming a customer or whatever issue, and we have to get them to quit reporting incorrect information. It was very frustrating. We were giving them the right information over and over again. They refused to fix the information."))

134. On or about November 4, 1999, Mr. Rowenhorst sent an email to Ms. Waterer, stating that a pharmacist had complained because he was not receiving the "correct reimbursement" from Florida Medicaid. (Fauci Exhibit 126) Mr. Rowenhorst testified that First Data Bank's continuing publication of Roxane's WACs was an "obstacle to reimbursement" and that removing the WAC pricing

was likely to result in higher reimbursement for at least some products. (Fauci Exhibit 128 (4/3/2003 James Rowenhorst Dep.), at 98:21 - 99:3 and 110:17 – 112:14)

Roxane's Response: Undisputed that the document and deposition testimony contain the quoted language. The Government's quotations, however, are selective and incomplete; the document and deposition testimony in their entirety are the best evidence of their respective content. Mr. Rowenhurst's e-mail relates to a reimbursement issue for lorazapam, a Roxane drug that is not at issue in this case. (*See, e.g.*, Fauci Ex. 126, 11/5/99 Paoletti Email to Waterer; Tab 251, 4/3/03 Rowenhorst Dep. 98-99, 110-12 (stating that his testimony on the subject concerned that "specific example")) As such this alleged fact is not material to the Government's motion for summary judgment or its claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). Moreover, the evidence indicates that Roxane attempted on numerous occasions to have First Databank remove the outdated WAC pricing. (Tab 275, 11/28/05 Waterer Dep. 239-42 ("[W]e had one heck of a time getting First Data Bank to report correct information. We went through their information and repeatedly told them that they were not reporting the correct information . . . . we had been consulting with our legal department to find out whether or not we would have to pursue legal remedy to get them to stop reporting false information . . . . What I took out of this was, here's another example that we have to go back to First Data Bank yet again. We have repeatedly given them the information, but now it's getting to the point where it's becoming a customer or whatever issue, and we have to get them to quit reporting incorrect information. It was very frustrating. We were giving them the right information over and over again. They refused to fix the information."))

135. On November 5, 1999, Ms. Paoletti notified Ms. Waterer that First Data Bank was now "willing to remove [Roxane's] WAC pricing from their database." (Fauci Exhibit 126) On or about December 7, 1999, Ms. Paoletti sent an email to Mr. Rowenhorst, stating that she had "received written confirmation from First Data Bank ***that all Multi-source product pricing except AWP has been updated to reflect a $0.00 price.***" (Fauci Exhibit 129) (emphasis supplied)

Roxane's Response: Undisputed.

136. Following Roxane's instruction to delete WACs, First Data Bank was left to publish only Roxane's AWPs for Roxane's multi-source products. (Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 527:5 - 527:15) Roxane elected to remove WAC pricing for its multi–source products even though it was aware that several states used WACs. (Fauci Exhibit 48)

Roxane's Response: Undisputed. However, Roxane states that States could have and did

request and receive WAC prices directly from Roxane. For example, Roxane provided WAC information to Massachusetts at its request. (Tab 288, Gilmore Ex. 9, 6/24/99 McCoy Letter to Massachusetts Medicaid re Updated WAC and AWP for Lithium Carbonate) In addition, certain States have passed laws requiring manufacturers to provide wholesale acquisition costs directly to State Medicaid programs, including Vermont and New Mexico. (Vt. Stat. Ann. Tit. 33 § 2010 (Vermont); N.M. Stat. § 27-2E-1 (New Mexico)

G. Roxane Knew or Should Have Known That Its Conduct Was Wrong

137. Roxane did not consider any laws or regulations relating in making decisions toset inflated AWPs. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 238:19 - 239:10, 283:4 - 283:19; Fauci Exhibit 130 (12/8/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 165:20 - 167:14, 142:20 - 144:3,208:8 - 208:18) Nor did Roxane review or rely upon reports from the Office of Inspector General, Department of Health and Human Services, or other governmental agencies relating to allegations or findings that AWPs were inflated. (*Id*.)

Roxane's Response: Roxane disputes the characterization that its AWPs were inflated. Roxane understood AWP to be a reference point generally tied to the branded version of a multisource drug. At launch Roxane generally set AWP at 10% below the corresponding brand's AWP. Roxane understood this to be the standard industry practice. (Roxane SOF at ¶ 99) Roxane believed that the industry and the Government shared its understanding of AWP. (Roxane SOF at ¶¶ 99-102) Ms. Waterer testified "[a]nd again, when you said you're using the term loosely AWP inflation, the industry understands what AWP is. It's a term that has been around for many, many, many years. And people in the industry and people that are familiar with AWP don't believe that AWP is an actual calculated average of some sort of pricing that wholesalers have to some sort of somebody else, and we don't believe that the government thinks that either. And there's a myriad of reasons why it would be irrational to believe that." (Fauci Ex. 130, 12/12/08 Waterer Dep. 142) Roxane also objects to the Government's characterization of its AWPs as "inflated" on the grounds that it is argument, not fact. *See Mercier v. Boilermakers Apprenticeship and Training Fund*, No. 07-cv-11307, 2009 WL 458556, at *9 (D. Mass. Feb. 10, 2009) (refusing to consider a summary judgment movant's argument reframed as facts).

Roxane disputes the Government's alleged fact that "Roxane did not consider any laws or regulations" when setting AWPs. The evidence proffered by the Government does not support this alleged fact and mischaracterizes the witnesses' testimony. Contrary to the Government's statements, Mr. Russillo testified that Roxane believed that it was in compliance with any relevant laws: "I was not aware of any laws that we would have been in danger of violating. We've talked about AWP. We were – we believed we were following all the requirements." (Fauci Ex. 13, 1/8/09 Russillo Dep. 283) Regarding the 2003 OIG report, Mr. Russillo testified that if there was any consideration to be made, Roxane "would have certainly taken that into account," and that he was "sure that [Roxane] had legal review of the guidance. And if there was anything that needed to be changed, we were told. But I don't recall being told to change

anything." (Tab 253, 1/8/09 Russillo Dep. 241-42)

Roxane does not dispute that Ms. Waterer testified that she did not rely upon Government reports when setting AWPs, and that she was unaware of specific individuals at Roxane who reviewed those reports. As stated above, however, Roxane believed that the Government shared its understanding, and the industry's understanding, of the term "AWP." (Fauci Ex. 13, 1/8/09 Russillo Dep. 283; Fauci Ex. 130, 12/12/08 Waterer Dep. 142) Indeed, the contents of reports from the Office of Inspector General, Department of Health and Human Services, and other governmental agencies relating to AWPs confirms Roxane's belief that the Government understood that AWP was not an average of actual acquisition costs. (*See generally* Roxane SOF at ¶¶ 1-95, 102)

138. By 1999, Roxane was aware that the government was investigating inflated AWPs in the pharmaceutical marketplace. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 54:19 - 54:22, 99:4 - 99:7, 172:13 - 172:16; Fauci Exhibit 2 (1/27/2005 Sheldon Berkle Dep.), at 229:16 - 229:13; Fauci Exhibit 131) Mr. Russillo, Roxane's director of multi-source marketing, testified that such investigations were a concern to him and to Boehringer Ingelheim in evaluating decisions regarding AWPs. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 166:7 - 166:9, 179:22 -180:16)

Roxane's Response: Undisputed that Roxane became aware that the Government was investigating "inflated AWPs" by the late 1990s. Roxane disputes any implicit characterization that its AWPs were inflated. (*See* Roxane's Resp. to US Roxane SOF at ¶ 137) Undisputed that Mr. Russillo testified that Government investigations were a concern to him in evaluating decisions regarding AWPs and that Boehringer Ingelheim was "sensitive" to AWP changes. (Fauci Ex. 13, 1/8/09 Russillo Dep. 180) Mr. Russillo did not testify that Boehringer Ingelheim "evaluated" decisions regarding AWPs.

Roxane further states that it understood AWP to be a reference point generally tied to the branded version of a multisource drug. At launch Roxane generally set AWP at 10% below the corresponding brand's AWP. Roxane understood this to be the standard industry practice. (Roxane SOF at ¶ 99) Roxane believed that the industry and the Government shared its understanding of AWP. (Roxane SOF at ¶ 99-102) Ms. Waterer testified "[a]nd again, when you said you're using the term loosely AWP inflation, the industry understands what AWP is. It's a term that has been around for many, many, many years. And people in the industry and people that are familiar with AWP don't believe that AWP is an actual calculated average of some sort of pricing that wholesalers have to some sort of somebody else, and we don't believe that the government thinks that either. And there's a myriad of reasons why it would be irrational to believe that." (Roxane SOF at ¶¶ 99-102; Tab 278, 12/12/08 Waterer Dep. 142) Mr. Russillo also testified that he "regarded any decision to raise AWPs as needing to be justified." (Fauci Ex. 13, 1/8/09 Russillo Dep. 166, 180) Further, Roxane believed that it was in compliance with any relevant laws, as Mr. Russillo testified: "I was not aware of any laws that

we would have been in danger of violating. We've talked about AWP. We were – we believed we were following all the requirements." (Tab 253, 1/8/09 Russillo Dep. 283)

139. In spite of such concerns, Roxane raised the AWPs on its furosemide products by as much as 300% in or around August 2000. (*See supra* Paragraph 84; *see also* Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 192:11 - 193:18) Roxane's new AWPs for its furosemide products were as much as 10 times larger than its sales prices to customers. (Fauci Exhibit 3 (Platt Decl.), A5 Summary)

Roxane's Response: Undisputed that Roxane raised its AWPs on the furosemide NDCs at issue in 2000. Roxane incorporates by reference its response to paragraph 84. Roxane disputes that its new AWPs for furosemide "were as much as 10 times larger than its sales prices to customers," because Roxane disputes that the "contract prices" in the Government's expert declaration accurately reflect Roxane's indirect contract prices to its customers for furosemide. (*See* Roxane's Responses to US Roxane SOF at ¶¶ 26, 32)

Roxane further states that after Roxane sets an AWP for a drug, it generally does not change its AWP. (*Id.* at ¶ 106) One exception to this practice is when a customer complains and points out that Roxane's AWP is significantly lower than its competitors. (*Id*.) In 2000, Roxane received customer complaints that its furosemide AWP was out of line with the AWPs for that drug in the rest of the market. (Tab 276, 5/9/07 Waterer Dep. 74-75) Roxane's furosemide AWPs were "significantly lower than [its] competitors' AWPs" and "so far out of line with [its] competitors" that pharmacies would not purchase its product, regardless of where the contract price was set. (Tab 248, 7/26/07 Paoletti Dep. 78) As explained by Ms. Waterer, "[i]f there was an exceptional instance where our pricing was out of line – I think I talked about, I believe it was Furosemide – in an exceptional case where it was brought to our attention, we might take steps to bring ourselves into the average or norm of what everyone else is doing." (Tab 276, 5/9/07 Waterer Dep. 103) As Ms. Waterer testified, Roxane "wanted to bring AWP into line with the competitors. The gist of it is that if we didn't do that, we were out of the market." (*Id.* at 201)

Disputed that the furosemide AWP increase is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide.

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to

Paragraph 74.

140. Mr. Russillo, who was involved in the decision to approve the increase in furosemide AWPs, testified that raising the AWP of a product to more than ten times its sales price did not concern him, so long as the AWP was increased to match a competitor's AWP. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 190:2 - 191:12 ("It doesn't matter what the number is. We were trying to be competitive."))

Roxane's Response: Undisputed that Mr. Russillo testified as described, but the Government's characterization and quotations are selective, incomplete and misleading. After Roxane sets an AWP for a drug, it generally does not change its AWP. (Roxane SOF at ¶ 106) However, in 2000, Roxane received customer complaints that its furosemide AWPs were out of line with the AWPs for that drug in the rest of the market. (Tab 276, 5/9/07 Waterer Dep. 74-75) Roxane's furosemide AWPs were "significantly lower than [its] competitors' AWPs" and "so far out of line with [its] competitors" that pharmacies would not purchase its product, regardless of where the contract price was set. (Tab 248, 7/26/07 Paoletti Dep. 78) As explained by Ms. Waterer, "[i]f there was an exceptional instance where our pricing was out of line – I think I talked about, I believe it was Furosemide – in an exceptional case where it was brought to our attention, we might take steps to bring ourselves into the average or norm of what everyone else is doing." (Tab 276, 5/9/07 Waterer Dep. 103) As Ms. Waterer testified, Roxane "wanted to bring AWP into line with the competitors. The gist of it is that if we didn't do that, we were out of the market." (*Id.* at 201) Mr. Russillo testified that he "regarded any decision to raise AWPs as needing to be justified," and that he would generally approve such an AWP change if it was necessary to keep Roxane's AWP in line with its competitors. (Tab 253, 1/8/09 Russillo Dep. 166, 180)

Disputed that the furosemide AWP increase is material to the Government's motion for summary judgment or its claims against Roxane. There were FULs was in place for many of the furosemide NDCs at issue for the majority of the relevant timeframe, and therefore Roxane's AWP was not the basis for Medicaid reimbursement. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). In addition, Roxane disputes that this alleged fact is material to the Government's Medicare claims against Roxane as the Government is not seeking Medicare damages with respect to furosemide.

UNITED STATES' REPLY: *See supra* United States' Reply to Roxane's Response to Paragraph 74.

141. Likewise, in or around June 2000, Mr. Rowenhorst circulated an email including a

Wall Street Journal Article entitled "Medicare Plans Major Overhaul, Targets Massive Overpayments." (Fauci Exhibit 132) The article specifically noted that "State and federal officials believe that some drug companies are reporting artificially inflated AWPs to industry guides that are used for government-reimbursement purposes." (*Id*.) Nevertheless, Mr. Rowenhorst recommended that Roxane continue to focus on higher AWPs as a way of staying competitive with Dey Laboratories in the home health care market:

> Depending on the results of HCFA's attempt to regulate prices for drugs in the Medicare program (see WSJ article below), the margins that the home health companies currently enjoy on the generic albuterol and ipratropium[] will be severely reduced. . .
>
> . . . In addition, generic ipratropium is not listed as a Federal Upper Limit Drug (otherwise known as Maximum Allowable Cost [MAC]) in the Medicaid system, however individual states have the authority to implement their own MACs.
>
> It is my recommendation, based on the reimbursement mechanisms in the retail, hospital and home health sectors, that we focus on a higher AWP and WAC and develop discount and rebate initiatives that will keep up compete [sic] with Dey in this market.

(*Id*.)

Roxane's Response: Undisputed that the email contains the quoted language. The Government's quotations and characterizations of the document, however, are selective, incomplete and misleading; the entirety of the document is the best evidence of its content. Roxane disputes the third sentence, that Mr. Rowenhorst made a recommendation to Roxane in the email. The portions of the email ***not*** quoted by the Government make clear that Mr. Rowenhorst's recommendation was that Roxane's affiliate company Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") "focus on a higher AWP and WAC" for BIPI's *brand* drug Combivent UDV – a product which never came to market and is not one of the subject drugs in this case. (Fauci Ex. 132, 6/6/00 Rowenhorst Email to Garofalo; Tab 252, 10/7/05 Rowenhorst Dep. 80, 162-63) The email was sent to three BIPI employees with the subject line "Combivent UDV Spreadsheet," and attaching that document. (Fauci Ex. 132, 6/6/00 Rowenhorst Email to Garofalo) Mr. Rowenhorst mentions the impact of possible regulations on generic albuterol and ipratropium reimbursement, not for the benefit of Roxane, but because BIPI's brand drug

Combivent competes "with Dey in this market." (*Id.*) Roxane disputes that either this statement of fact or Fauci Exhibit 132 are material to the Government's motion for summary judgment because it does not relate to Roxane or a Roxane drug at issue. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts).

VI. ROXANE'S FALSE AWPs FOR ITS IPRATROPIUM BROMIDE PRODUCTS CAUSED THE MEDICARE PROGRAM TO PAY MORE THAN IT WOULD HAVE PAID ABSENT THE FALSITY

142. The Court is respectfully referred to Paragraphs 1-16 of the United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants (US-C-SF) for certain facts concerning Medicare Part B payment for DME drugs.

Roxane's Response: This paragraph does not state a purported statement of fact and therefore no response is required. Roxane respectfully refers the Court to its responses and objections to paragraphs 1-16 of the Government's Common Statement of Material Facts.

143. During the relevant time period, Medicare Part B paid claims for ipratropium bromide, when used in connection with durable medical equipment. (Henderson Common Exhibit 3 (Declaration of Carolyn Helton (hereinafter, "Helton Decl.")), ¶ 3) There were three different HCPCS codes used to process claims for ipratropium bromide. The HCPCS code J7645 was used from January 1, 1995 through March 31, 1997. The HCPCS code K0518 applied from April 1, 1997 through December 31, 1999. The HCPCS code J7644 applied from January 1, 2000, through the present. (*Id*., ¶ 16)

Roxane's Response: Undisputed that the listed HCPCS codes applied to ipratropium bromide during the relevant time period. Roxane objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery and contradicts pre-existing facts in the record, and because Roxane has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

Undisputed that Medicare Part B paid for some claims for ipratropium bromide when used in connection with durable medical equipment. However, Roxane disputes this paragraph to the extent it implies that Medicare Part B paid for all claims for reimbursement for ipratropium bromide when dispensed via durable medical equipment. In fact, ipratropium bromide dispensed via durable medical equipment in hospitals was also reimbursed under Medicare Part A or as part of a bundled package under the Medicare Part B OPPS system. (*See* Roxane SOF at ¶¶ 151-55 (not disputed by the Government))

UNITED STATES' REPLY: Roxane's objection to the Declaration of Carolyn Helton is baseless. Defendants took her deposition on March 13, 2008, and had every opportunity to question her about Medicare reimbursement.

144. The DMERC for Region D, CIGNA Government Services, Inc. ("CIGNA"), paid on behalf of Medicare many provider claims for reimbursement for ipratropium bromide. (Fauci Exhibit 134 (Declaration of Ian Dew (hereinafter, "Dew Decl.")) ¶¶ 9-13 and Exhibits C and D thereto)

Roxane's Response: Undisputed that CIGNA paid some claims for reimbursement for ipratropium bromide. However the fact that "many provider claims" were paid by CIGNA is not supported by the Government's proffered evidence. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006) (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule 56.1). Roxane further objects to the Government's reliance on a new declaration from Ian Dew which was submitted after the close of discovery and with respect to which Roxane did not have the opportunity to conduct discovery.

145. CIGNA reimbursed for covered drugs at the lower of the allowable amount calculated by the carrier or the amount submitted by the provider in the claim. (Henderson Common Exhibit 3 (Helton Decl.), ¶ 3)

Roxane's Response: Disputed. Roxane objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery and contradicts pre-existing facts in the record, and because Roxane has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

Roxane further states that this alleged fact is not supported by the Government's proffered evidence, which merely states that "Medicare Part B reimbursement" is based on these values and not that CIGNA paid for reimbursement based on these amounts. Helton testified at her deposition that if a provider submitted an amount that was "lower than the amount that [she] came up with using AWP," CIGNA would pay "the submitted amount" and not "the AWP amount." (Tab 236, 3/13/08 Helton Dep. 173)

UNITED STATES' REPLY: Roxane's objection to the Declaration of Carolyn Helton is baseless. Defendants took her deposition on March 13, 2008, and had every opportunity to question her about Medicare reimbursement.

146. CIGNA performed drug pricing calculations using AWP data obtained from Red

Book. (*Id.*, ¶ 9) In general, CIGNA performed drug pricing updates quarterly.

Roxane's Response: Undisputed that CIGNA obtained AWPs from Red Book, but Roxane objects that this paragraph is incomplete. Helton actually testified at her deposition that CIGNA obtained AWPs from both paper and CD versions of Redbook. (Tab 236, 3/13/08 Helton Dep. 36-37, 44-45) Helton further stated that she never contacted drug manufacturers to verify the pricing information in her arrays. (*Id.* at 38) Helton did not know how Red Book received prices from the manufacturers. (*Id.* at 237) Roxane objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery and contradicts preexisting facts in the record, and because Roxane has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

Undisputed that CIGNA generally, but not always, performed drug pricing updates quarterly, although the Government has offered no evidentiary support for that claim. *See O'Brien*, 440 F. Supp. 2d at 5 n.1 (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule 56.1). In fact, Helton testified that at first, CIGNA updated the array sheets monthly, and eventually moved to doing updates quarterly. (Tab 236, 3/13/08 Helton Dep. 150, 159-60) But for certain quarters Helton would simply check to see if anything changed rather than preparing a new array for that quarter. (*Id.* at 221)

UNITED STATES' REPLY: Roxane's objection to the Declaration of Carolyn Helton is baseless. Defendants took her deposition on March 13, 2008, and had every opportunity to question her about Medicare reimbursement.

147. Generally, to determine the allowable fee for a particular DME drug, CIGNA used the Red Book to select the NDCs falling within the narrative description of the HCPCS code. CIGNA then created an array of prices that included the AWP for each selected NDC, using Red Book data. CIGNA converted each AWP to a unit price, so that there was a common measure of price. (*Id.*, ¶¶ 9-10)

Roxane's Response: Undisputed that this paragraph sets forth CIGNA's general methodology for creating the pricing arrays but Roxane objects that this paragraph is incomplete. Helton also testified that she would have to use her discretion when deciding, based on the narrative description in Red Book, whether or not to add a price to a particular array. (Tab 236, 3/13/08 Helton Dep. 150-51) Roxane objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery and contradicts pre-existing facts in the record, and because Roxane has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

UNITED STATES' REPLY: Roxane's objection to the Declaration of Carolyn Helton

is baseless. Defendants took her deposition on March 13, 2008, and had every opportunity to question her about Medicare reimbursement.

148. Using the array, CIGNA then determined the median AWP for the NDCs in the array. If there was only one NDC with a published AWP in the array, CIGNA selected that price as the median. If there was an odd number of NDCs in the array, CIGNA selected the middle price. If there was an even number of NDCs in the array, CIGNA took the average of the middle two NDC prices to achieve a median. (*Id*., ¶ 11)

Roxane's Response: Undisputed that CIGNA used this methodology for calculating the median. Roxane objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery and contradicts pre-existing facts in the record, and because Roxane has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

UNITED STATES' REPLY: Roxane's objection to the Declaration of Carolyn Helton is baseless. Defendants took her deposition on March 13, 2008, and had every opportunity to question her about Medicare reimbursement.

149. The precise method followed by CIGNA for determining allowable reimbursement rates changed in the 1996-2003 period, in accordance with changing regulations or CMS instructions. (*Id*., ¶ 12)

Roxane's Response: Undisputed that CIGNA may have implemented some changes in accordance with new regulations or CMS instructions, but Roxane objects to and disputes the inference or suggestion that CIGNA always followed all applicable regulations or instructions. For example, Helton testified that she determined whether a drug is a brand name by looking at whether the drug cross-referenced another drug using the word "see" in the printed Red Book. (Roxane SOF at ¶ 181; Tab 236, 3/13/08 Helton Dep. 151-52, 254-55) Roxane objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery and contradicts pre-existing facts in the record, and because Roxane has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

UNITED STATES' REPLY: Roxane's objection to the Declaration of Carolyn Helton is baseless. Defendants took her deposition on March 13, 2008, and had every opportunity to question her about Medicare reimbursement.

150. From 1994 through December 31, 1997, CIGNA calculated the allowable reimbursement rate as 100% of the median AWP of the generic forms of the drug (unless, as indicated above, only a brand drug was available). (*Id*., ¶ 13)

Roxane's Response: Undisputed. Roxane objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery and contradicts pre-existing facts in the record, and because Roxane has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

UNITED STATES' REPLY: Roxane's objection to the Declaration of Carolyn Helton is baseless. Defendants took her deposition on March 13, 2008, and had every opportunity to question her about Medicare reimbursement.

151. Beginning January 1, 1998, as a result of the Balanced Budget Act of 1997, the DMERCs began paying providers at ninety-five percent of the median AWP. Accordingly, for quarters beginning January 1998, CIGNA calculated the allowable fee by multiplying the median AWP by 0.95. (*Id*., ¶ 13)

Roxane's Response: Undisputed. Roxane objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery and contradicts pre-existing facts in the record, and because Roxane has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

UNITED STATES' REPLY: Roxane's objection to the Declaration of Carolyn Helton is baseless. Defendants took her deposition on March 13, 2008, and had every opportunity to question her about Medicare reimbursement.

152. Effective approximately January 1999, HCFA issued instructions to the DMERCs that the allowable fee was to be determined as the lower of the median of the generic sources of the drug or the lowest priced brand name AWP. (*Id*., ¶ 13, and at Helton Exhibit D) The transmittal further stated, "[a] brand name product is defined as a product that is marketed under a label name that is other than the generic chemical name for the drug or biologica1." (*Id*.)

Roxane's Response: Undisputed. The Government's quotation, however, is selective, incomplete and misleading. The entirety of the instruction is the best evidence of its content. The full definition provides: "A brand name product is defined as a product that is marketed under a label name that is other than the generic chemical name for the drug or biologica1. If a manufacturer chooses to market its product under a proprietary name rather than the generic

chemical name of the drug, we believe this is a brand. (Roxane SOF at ¶ 175-75; US Resp. to Roxane SOF at ¶ 174; 63 Fed. Reg. 58814, 58849-850) Roxane objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery and contradicts pre-existing facts in the record, and because Roxane has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

UNITED STATES' REPLY: Roxane's objection to the Declaration of Carolyn Helton is baseless. Defendants took her deposition on March 13, 2008, and had every opportunity to question her about Medicare reimbursement.

153. The same instruction was repeated in Transmittal No. AB-99-63. (Fauci Exhibit 39)

Roxane's Response: Undisputed. *See* Response to ¶ 152.

UNITED STATES' REPLY: Roxane's objection to the Declaration of Carolyn Helton is baseless. Defendants took her deposition on March 13, 2008, and had every opportunity to question her about Medicare reimbursement.

154. Once CIGNA determined a new allowable fee for a HCPCS code, the new or updated price was entered into the electronic claims processing system used by the DMERCs for paying Part B claims, referred to as the ViPS Medicare System. Once a new or updated allowable fee was entered, the ViPS Medicare System used that price for determining the reimbursement of all applicable Medicare Part B claims that had not already been processed through the pricing part of the system. (Henderson Common Exhibit 3 (Helton Decl.), ¶ 14)

Roxane's Response: Disputed that this paragraph is material to any of the Government's claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); St. Paul *Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). Roxane objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery and contradicts pre-existing facts in the record, and because Roxane has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

UNITED STATES' REPLY: Roxane's objection to the Declaration of Carolyn Helton is baseless. Defendants took her deposition on March 13, 2008, and had every opportunity to

question her about Medicare reimbursement.

155. The arrays used by CIGNA to determine the allowable amount for ipratropium bromide from the third quarter of 1996 ("1996 Q3") through 2003 Q4 are at Exhibit A to the Declaration of Carolyn Helton, the CIGNA DMERC pricing analyst. (*Id*., ¶ 16)

Roxane's Response: Undisputed that these documents represent arrays used by CIGNA to determine the allowable amount during the relevant period.

However, this paragraph is incomplete insofar as it fails to mention that one array used for a full year from Q2 1997 through Q2 1998 was actually created by Administar. (Tab 236, 3/13/08 Helton Dep. 61, 217-219) Roxane objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery and contradicts preexisting facts in the record, and because Roxane has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

UNITED STATES' REPLY: Roxane's objection to the Declaration of Carolyn Helton is baseless. Defendants took her deposition on March 13, 2008, and had every opportunity to question her about Medicare reimbursement.

156. For quarters prior to 1997 Q2, the only product in the relevant array is Atrovent, the brand product marketed by Roxane's parent company, Boehringer Ingelheim Corp. Therefore Roxane's reported prices had no impact on the amounts paid by CIGNA for ipratropium bromide for claims processed before April 1, 1997.

Roxane's Response: Undisputed that Atrovent is a brand product or that Roxane's reported prices had no impact on the amounts paid by CIGNA for any claims processed before April 1, 1997. However, Roxane disputes and objects to the remainder of this paragraph on grounds that it is unsupported by citations to the record, as is required by Local Rule 56.1. *See O'Brien*, 440 F. Supp. 2d at 5 n.1 (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule 56.1). Roxane further disputes that Atrovent was marketed by Boehringer Ingelheim, Corp. Boehringer Ingelheim Corp. does not market or sell any drugs. (BIC & BIPI SOF at ¶ 3)

157. For each the arrays for the quarters from 1997 Q2 through 2003 Q4, Roxane's products did appear in the arrays. (*Id*., Exhibit A thereto) Dey's ipratropium bromide products also appeared in the arrays.

Roxane's Response: Undisputed that Roxane's ipratropium bromide products appeared in CIGNA's arrays from 1997 Q2 through 2003 Q4.

However, Roxane disputes that the alleged fact that Dey's products were in CIGNA's arrays is material to the Government's Medicare claims against Roxane. *See* Local Rule 56.1 (requiring summary judgment movant to "include a concise statement of the *material* facts of record as to which the moving party contends there is no genuine issue to be tried") (emphasis added); *St. Paul Fire & Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider a summary judgment movant's immaterial facts). Roxane objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery and contradicts pre-existing facts in the record, and because Roxane has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

UNITED STATES' REPLY: Roxane's objection to the Declaration of Carolyn Helton is baseless. Defendants took her deposition on March 13, 2008, and had every opportunity to question her about Medicare reimbursement.

158. All of the arrays from 1997 Q2 through 2003 Q4 show the same median generic unit price, $3.52 per milligram, for K0518 and J7644. (*Id*., Exhibit A thereto) During the period 1997 Q2 through December 31, 1997, the allowable amount determined by CIGNA for K0518 and J7644 was 100 percent of the median, or $3.52 per milligram. (*Id*.)

Roxane's Response: Undisputed that CIGNA showed the median generic price at $3.52 per milligram from 1997 Q2 through 2003 Q4 or that CIGNA calculated the allowable amount for K0518 and J7644 to be $3.52 until December 31, 1997. However, Roxane objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery and contradicts pre-existing facts in the record, and because Roxane has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

UNITED STATES' REPLY: Roxane's objection to the Declaration of Carolyn Helton is baseless. Defendants took her deposition on March 13, 2008, and had every opportunity to question her about Medicare reimbursement.

159. After January 1, 1998 (the effective date of the Balanced Budget Act of 1997), the allowable amount determined by CIGNA for K0518 and J7644 was 95 percent of $3.52, or $3.34. (*Id*.)

Roxane's Response: Undisputed that CIGNA calculated the allowable amount for K0518 and J7644 to be $3.34 in January 1998. Roxane objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery and contradicts pre-existing facts in the record, and because Roxane has not yet had the opportunity to conduct

discovery with respect to Ms. Helton's declaration.

160. For the period 1997 Q2 through 2001 Q3, any reduction of one percent or more in the AWPs of the Roxane products (whether the AWP is expressed as a unit price or as the package price) would have lowered the median and therefore the Medicare allowed amount. (*Id*., ¶ 24)

Roxane's Response: Disputed that any reduction in its AWPs would have translated into a lower median or a lower Medicaid reimbursement because the Government has not introduced any competent evidence supporting that fact. *See O'Brien*, 440 F. Supp. 2d at 5 n.1 (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule 56.1). Roxane objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery and contradicts pre-existing facts in the record, and because Roxane has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

161. During the period April 1, 1997, through September 30, 2001, CIGNA processed for payment 1,076,790 claims for reimbursement for HCPCS codes K0518 or J7644. Of these, 910,835 claims were paid based on an allowed unit amount of either $3.52 or $3.34. (Fauci Exhibit 134 (Dew Decl.), ¶ 14)

Roxane's Response: Disputed, because the number of claims processed by CIGNA is unsupported by competent evidence in the record. The Government has offered no authenticated documents or testimony of a person with knowledge of these figures. Instead, the Government improperly seeks to support this fact with an opinion without any factual basis. *See Schubert v. Nissan Motor Corp.*, 148 F.3d 25, 31 (1st Cir. 1998) (affirming district court's exclusion of affidavits produced on summary judgment as improper testimony because they were not based on firsthand knowledge of the affiant). Roxane further objects to the Government's reliance on a new declaration from Ian Dew which was submitted after the close of discovery and with respect to which Roxane did not have the opportunity to conduct discovery.

DATED: September 22, 2009 Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s James J. Fauci
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Dated: September 22, 2009